Thesis for doctoral degree (Ph.D.)
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# Orbital Blow Out Fracture

## To operate or not to operate – that is the question

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# Orbital Blow Out Fracture
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## THESIS FOR DOCTORAL DEGREE (Ph.D.)

by

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*The dissertation will be held on*:
Thursday June 22nd, 2017. 09:00 -12:00
Nanna Svartz Aula, Karolinska University Hospital, Solna

*To my daughter Delsa*

# ABSTRACT

When the eye socket is exposed to severe blunt trauma the pressure in the socket increases. As a protection mechanism to prevent the eye from disruption, the thin bony walls surrounding the eye fracture. Such a fracture is called Blow Out Fracture (BOF). It is well known that a significant BOF needs surgical treatment otherwise it may lead to double vision and aesthetic deformities such as sunken eye. Furthermore, small BOF are not considered to need any surgical treatment and will heal without any remaining symptoms. It is highly important to differentiate which patients need to be operated on or which do not. This has been the subject of several studies over the past few decades.

The overall aim of this thesis has been to identify which patients with BOF need an operation and which do not require an operation to prevent functional and aesthetic disorders.

In paper I we found that the amount of displaced orbital tissue (herniation) and the relative change in the orbital volume due to trauma may be insufficient predictors to use when differentiating if a patient needs surgical or non-surgical treatment.

In Paper II we concluded that there is a clear agreement that surgery within 24h is needed when motility of the eye is hindered. Regarding the management of the remaining patients with BOF, there are considerable differences in opinion between the surgeons, specialties and countries, despite existing recommendations.

In paper III we found that in the case of entrapment with restriction of eye motility, there is a need for surgical treatment performed by an experienced surgeon as soon as possible, but not necessarily within 24h. Furthermore, we found that double vision due to eye motility restriction caused by impingement is not an ophthalmologic emergency and surgery is recommended if the diplopia and eye motility is not improved over time. We also found that the surgical reduction of all impinged or entrapped tissue is at least as important as surgical timing for the outcome.

In paper IV-V we performed prospective cohort and controlled randomized studies on patients with BOF. We found a significant correlation between CT scan findings on presentation to aesthetic outcome, namely patients who developed cosmetic problems compared to those patients who did not develop any cosmetic problems. We could therefore conclude that BOF patients with the following findings have a substantial risk for the development of cosmetic deformities and surgical treatment needs to be considered:

- Isolated inferior wall fracture with a herniation < 1.0 ml and a fracture area ≥ 2.3 $cm^2$.
- Isolated inferior wall fracture with a herniation ≥ 1.0 ml and a fracture distance from inferior orbital rim to the posterior edge of the fracture ≥ 3.0 cm.
- Inferomedial fracture with a herniation ≥ 0.9 ml.

We also found that double vision in BOF, without eye motility limitation, is due to edema and it is not an indication for surgery. The statement that, sunken eye (enophthalmus) will lead to double vision could not be supported by our data. On the contrary, none of the patients with late enophthalmus had double vision and none of patients with double vision had enophthalmus. Furthermore, we found that delayed correction of BOF appears to have the same aesthetic outcome as early corrections, if the surgical correction is performed immediately after the

aesthetic deformities are discovered. Therefore, BOF patients require a close follow-up of, as a suggestion 1 and 3 months post-injury.

In this project, we have provided an algorithm based on available evidence to predict which patients with BOF benefit from surgical vs non-surgical treatment.

In summary, when deciding whether to operate or not on a BOF, it is important to recognize that a surgical indication upon functional impairment is limited to muscle motility restriction due to entrapment or impingement. Other functional impairment is generally benign and will resolve over time. Regarding the decision making around surgical treatment due to aesthetic deformities, patient´s involvement is crucial since the patient´s experience of the importance of facial asymmetry is individual and this may differ from the surgeons´ opinion.

# LIST OF PUBLICATIONS

This thesis is based on the following studies, which will be referred to in the text by their roman numerals:

I. Babak Alinasab, Mats O. Beckman, Tony Pansell, Saber Abdi, Anders H. Westermark, Pär Stjärne.
**Relative Difference in Orbital Volume as an Indication for Surgical Reconstruction in Isolated Orbital Floor Fractures.** Craniomaxillofac Trauma Reconstr. 2011 Dec; 4(4): 203-12.

II. Babak Alinasab, Michael Ryott, Pär Stjärne
**Still No Reliable Consensus in Management of Blow-Out Fracture.**
Injury. 2014 Jan; 45(1):197-202.

III. Babak Alinasab, Abdul Rashid Qureshi, Pär Stjärne.
**Prospective Study on Ocular Motility Limitation Due to Orbital Muscle Entrapment or Impingement Associated with Orbital Wall Fracture.**
DOI.org/10.1016/j.injury.2017.04.039

IV. Babak Alinasab, Karl-Johan Borstedt, Rebecka Rudström, Michael Ryott, Abdul Rashid Qureshi, Mats O. Beckman, Pär Stjärne.
**New Algorithm for Management of Orbital Blow Out Fracture Based on Prospective Study.**
Submitted.

V. Babak Alinasab, Karl-Johan Borstedt , Rebecka Rudström, Michael Ryott, Abdul Rashid Qureshi, Pär Stjärne.
**Prospective Randomized Controlled Pilot Study on Orbital Blow out Fracture.**
Submitted.

# CONTENTS

# LIST OF ABBREVIATIONS

| | |
|---|---|
| AUC | Area under the curve |
| BOF | Blow Out Fracture |
| CT | Computed tomography |
| h | Hours |
| ICC | Interclass correlation coefficient |
| k | Kappa |
| ml | $cm^3$ |
| No VD | No visible deformity |
| ROC | Receiver operating characteristics |
| VD | Visibel deformity |

# INTRODUCTION

## BACKGROUND

Isolated orbital wall fracture, also referred to as blow out fracture (BOF) are common findings in facial trauma caused by fall, assault, traffic accident or sport injury. It is seen more often in men than women but not uncommon in children. Severe orbital trauma with BOF may lead to blindness. However, it more commonly leads to other functional disorders such as, reduced visual acuity, ocular motility limitation, diplopia and hypesthesia of infraorbital nerve. BOF is also associated with aesthetic deformities such as enophthalmus, hypoglobus and superior sulcus deformity.

To prevent the development of aesthetic deformities, repair of fractured orbital walls is recommended. It is well known that a small BOF is treated non-surgically and it heals without any remaining symptoms, while a significant BOF needs surgical reconstruction. Therefore, it is highly important to differentiate which patient needs surgical or non-surgical treatment and this has been the subject of several studies for decades. For a large part of the 20$^{th}$ century BOF was routinely managed with early surgery until 1974 when Putterman [1] in a prospective study showed that most of the BOF healed without any major functional or aesthetic symptoms. This study resulted in a more conservative management of BOF patients, until the computed tomography (CT) scan became the golden standard diagnostic method of BOF. The CT scan provided the surgeons with detailed information about the extent of the BOF that they had not had access to before. Based on the CT scan findings, several different expert opinions on when to surgically reconstruct BOF were launched. This resulted in a situation with different management of BOF patients depending on the surgeon.

During the last years options for different treatment and surgical devices have increased, but the timing and the indications for surgical reconstruction still remain controversial [2]. Early assessment of the significance of a BOF and decision on surgical or non-surgical treatment have been said to be crucial for an optimal result. Due to the lack of evidence there are considerable differences in opinion regarding the management of BOF patients. Thus, there is a lack of a reliable consensus.

# EPIDEMIOLOGY

Different factors such as social characteristics, demographics, time of the study and culture associated with facial trauma influence the epidemiologic picture of patients with facial fractures [3]. In Iran, motor vehicle accidents were the leading cause of facial fractures (54%) followed by falls and assaults [4]. A Swedish study conducted between 1986-1996 reported road traffic accident as leading cause of injury [5]. According to an unpublished data, assault was the most common cause of injury in between young patients, while falling was the most common cause of injury among elderly patients in Stockholm, Sweden, in 2006. In a study of soldiers in the US army, assault was the most common cause of injury [6]. In the pediatric population sports accident have been reported to be the leading cause of orbital fractures [7].

# ANATOMY OF THE ORBIT

The orbit can be described at a four-sided pyramid with an apex posteriorly, a base anteriorly with an axis tilted medially (figure 1).

The orbit can be compared to a box with precious content enveloped in fat tissue and protected by the eyelid. Orbital´s structures are arranged in groups of seven: seven bones, seven ocular muscles and seven nerves [8]. The orbits shape and size varies through the live. The orbital volume increases rapidly up to age of 12 [9, 10]. It is reported that the orbital growth stop at age of 11 in girls and at age of 15 in boys [9]. By aging, the skeletal morphology of the orbits and the deep orbital fat change, leading to changes in the appearance [11, 12].

**ORBITAL BONES**

Seven bones form the orbit (figure 2). The floor is made up of zygoma, maxilla and the palatine, the medial wall of the lacrimal, ethmoidal bones, the roof of lesser wing of sphenoid and frontal bone and the lateral wall of zygoma and great wing of sphenoid. The medial orbital wall is about a half of the lateral orbital wall´s height since the inferior orbital wall tips upwards medially in about $45^{o}$ [13]. Although the lamina papyracea on the medial wall is the thinnest (0.2-0.4 mm) orbital wall, the BOF more commonly occurs in the floor (0.5-1.0 mm) medial to infra orbital nerve canal (figure 3) [14-16]. In contrast to the inferior orbital wall, the medial orbital wall is supported by the multiple bony septae within the ethmoidal sinus [17]. The orbital floor lateral to the infraorbital canal is thicker compared to the medial floor. Therefore, fracture in this area is uncommon. However, anatomical weakness in the lateral portion of the infraorbital nerve may be the mechanism behind lateral fractures [18].

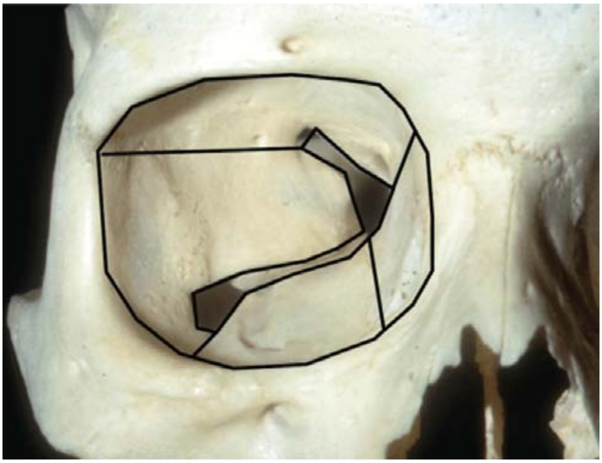


*Figure 1.*
*The orbital pyramid tilted medially. A modified figure, originally from:*
*Carolina Martins et al, Micro-surgical Anatomy of the Orbit: rule of Seven [8].*

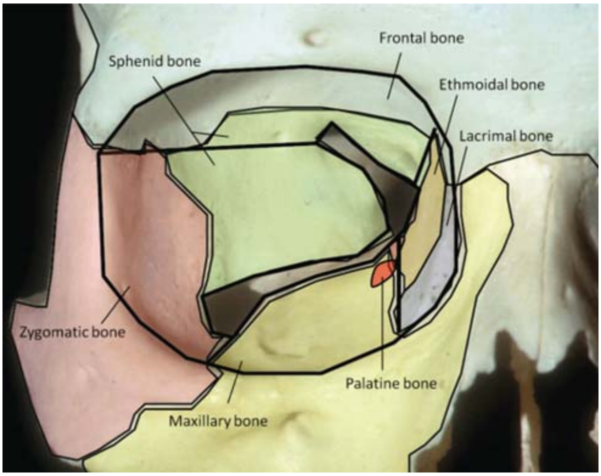



*Figure 2.*
*The 7 bones forming the orbit. A modified figure, originally from: Carolina Martins et al, Microsurgical Anatomy of the Orbit: rule of Seven [8]).*

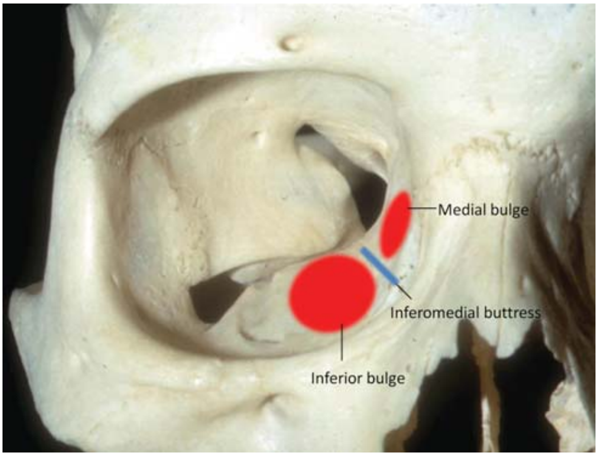



*Figure 3.*
*The inferomedial buttress in between the inferior and medial bulge where the BOF usually occur.*

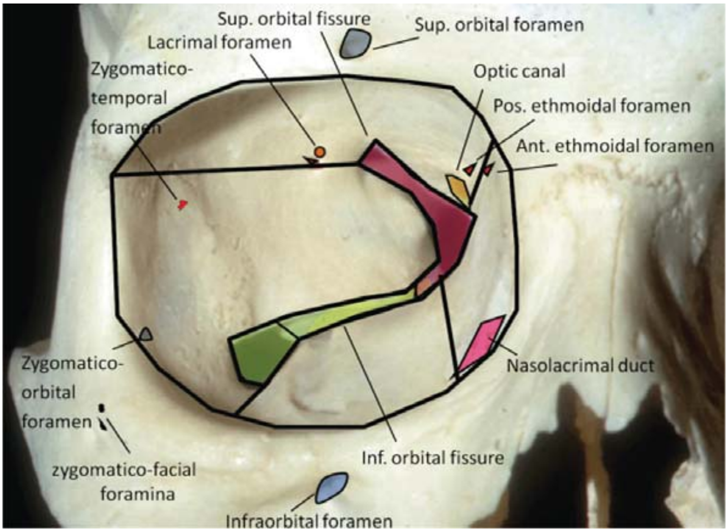



*Figure 4. The openings in the orbit. A modified figure, originally from: Carolina Martins et al, Microsurgical Anatomy of the Orbit: rule of Seven [8]).*

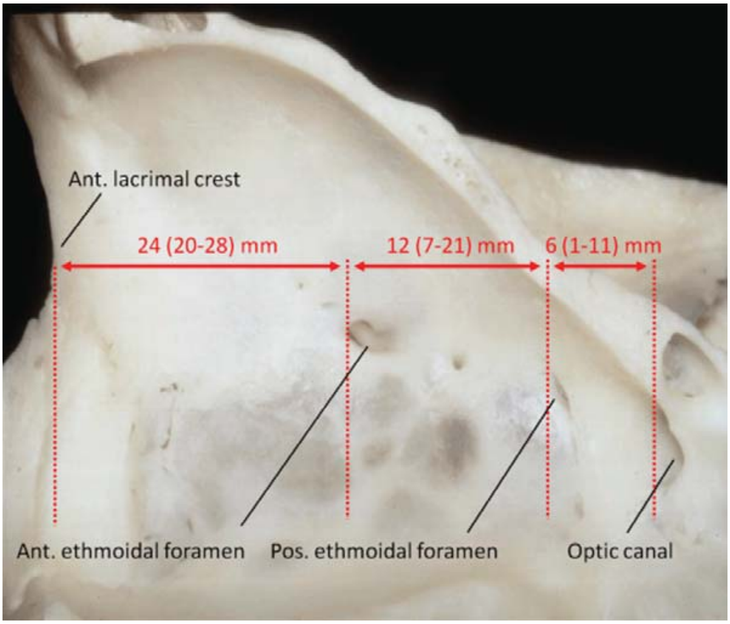



*Figure 5. Sagittal cut of the left orbit showing the medial wall and the measurements between the vital structures. A modified figure, originally from: Carolina Martins et al, Microsurgical Anatomy of the Orbit: rule of Seven [8]).*

## ORBITAL OPENINGS

On each one of the four orbital walls, there are openings for passage of nerves and vessels of highly importance to be recognized.

*Inferiorly*

Between the lateral wall and the floor the inferior orbital fissure (green) is located. The periorbit continues downward into the fissure. To expose the orbital floor the contents of the inferior orbital fissure may be safely incised after bipolar cautery [19]. The infraorbital foramen (blue) is located about 1cm below the inferior orbital rim on the base on the orbit (figure 4).

*Medially*

The opening of the nasolacrimal duct (pink) is located between the inferior orbital floor and the medial wall. Between the medial orbital wall and the roof on an average distance of 24 mm from anterior lacrimal crest the anterior ethmoidal foramen (red) is found. 12 mm posterior, the posterior ethmoidal foramen (red) is located and 6 mm posterior to that is the optic canal (yellow) (figure 4) [20]. However, the anatomy of the foramens in the medial wall can vary. About 16% of the patients have no anterior ethmoidal foramen and 30% have multiple foramina [21].

*Laterally*

The zygomatico-orbital foramen (gray), and the zygomatico-facial (black) foramina are found inferiorly on the lateral wall. The zygomatico-temporal foramen is located superior to the zygomatico-orbital foramen (red) (Figure4).

*Superiorly*

Between the lateral wall and the roof is the lacrimal foramen (orange) and the superior orbital fissure (purple). The supra-orbital foramen (dark blue) is found about 5 mm from the superior orbital rim in the same sagittal plane as inferior orbital foramen on the base of the orbit (figure 4).

## DISTANCES IN THE ORBIT

There are danger areas in the orbit. The possibility to injure the vital structures in the orbit creates a fear. It is crucial to understand the orbital measurements to achieve a successful
orbital reconstruction.

*Inferior orbital wall*

A fix point to measure the distances to the structures along the inferior orbital wall is the infraorbital foramen. The distance from infraorbital foramen to the lateral margin of the lacrimal fossa is 13 (8-18) mm. Inferior orbital fissure is 24 (20-27) mm from this foramen. Posterior wall of the maxilla lies 36 (26-44) mm from this point. The distance from infraorbital orbital foramen to the optic canal is 48 (40-54) mm (figure 5). The coved portion of the infraorbital nerve is 14 (8-28) mm [20].

*Medial orbital wall*
Anterior lacrimal crest is a distinct anatomical structure to measure the anatomical landmarks on the medial wall. From this point to the anterior ethmoidal foramen is 24 (20-28) mm, to the posterior ethmoidal foramen 36 (29-40) mm and to the optic foramen 42 (37-48) mm (figure 5) [20].

*Lateral orbital wall*
From the fontozygomatic suture to the lacrimal foramen is 25 (12-33) mm. The superior orbital fissure lies 35 (28-38) mm from this point. The distance from the optic canal to this point is 43 (39-46) mm [20].

*Superior orbital wall*
From the superior orbital notch or foramen on a distance of 32 (28-41) mm the lacrimal foramen is found. The superior orbital fissure lies 40 (35-45) mm from this foramen. The distance to optic canal is 45 (40-50) mm from this point [20].

## ORBITAL MUSCLES

There are seven intraorbital muscles: levator palpebrae, superior, inferior, lateral, and medial rectus, and superior and inferior oblique muscles. These muscles attach around the orbital apex (the annulus of Zinn) (figure 7), except the inferior oblique muscle which attaches to the medial orbital wall. The superior oblique muscle passes through a tendon (trochlea) attached to superomedial orbital wall (figure 6). An orbital wall fracture in this area may result in limitation downward gaze [8]. The four rectus muscles form a *muscle cone* from apex to their attachment on the eyeball.

Each rectus muscle is surrounded by fibrous capsule which are attached to each other by a thin membrane called the *intermuscular septum*. The orbital fat is divided by the intermuscular septum into *intraconal* and *extraconal* fat. *Tenon´s capsule* is a thin membrane that envelopes the eyeball from where the optic nerve enters the eyeball to the limbus. The Tenon´s capsule and the intermuscular septum fuse to each other 3 mm from limbus [22]. The orbicularis oculi muscle is on the base of the orbital pyramid.

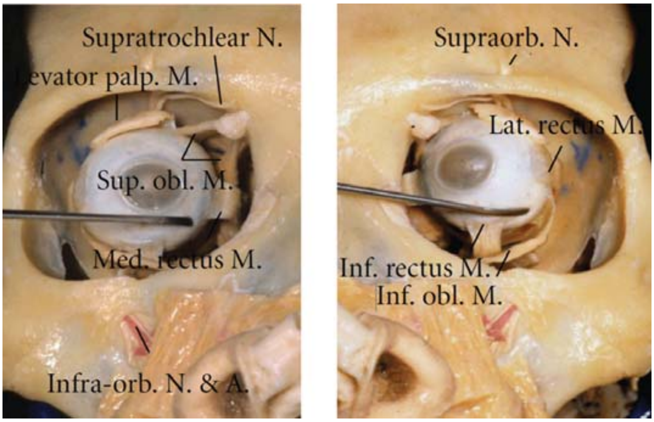



*Figure 6.*
*Orbital muscles (except orbicularis oculi) and visible nerves on a frontal view. A modified figure, originally from: Carolina Martins et al, Microsurgical Anatomy of the Orbit: rule of Seven [8]).*

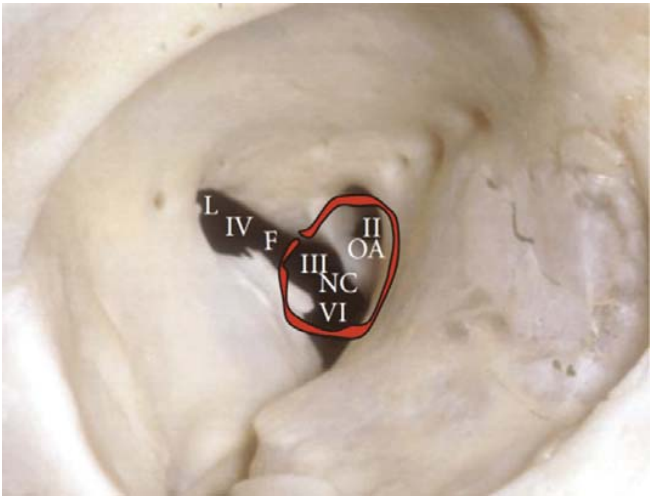



*Figure 7.*
*Orbital nerves passing inside the annulus of Zinn (red) or outside the annulus of Zinn. A modified figure, originally from: Carolina Martins et al, Microsurgical Anatomy of the Orbit: rule of Seven [8]).*

The eyeball and the orbital muscles are surrounded and anchored by connective tissue to the orbital wall. An impingement of this connective tissue or orbital fat in a BOF is believed to cause orbital motility limitation [23].

**ORBITAL NERVES**

There are seven orbital nerves: optic nerve (II), oculomotor (III) and abducens (VI) nerves, nasociliary (NC) which all pass inside the annulus of Zinn; the trochlear (IV), the frontal (F) and lacrimal (L) nerves which pass outside the annulus. All the nerves enter the orbit through the superior orbital fissure, except the optic nerve, which enters into the orbit through the optic canal [8].

# TYPES OF FRACTURES

There are 2 types of orbital wall fractures: pure and impure. Impure BOF are those that involve orbital rim(s). Pure orbital fractures involve only internal orbital walls and are also called Orbital Blow out Fractures (BOF). A BOF occurs commonly in inferior (figure 8 A), medial (figure 8 B) or inferomedial (figure 8 C) orbital walls where the bones are thinnest.

The inferomedial buttress divides the inferior orbital wall (or floor) from the medial wall. The inferior and/or medial bulge is involved in a BOF (figure 3). The incidence of medial BOF is less because of the multiple bony septae within the ethmoidal sinus supporting it [17].

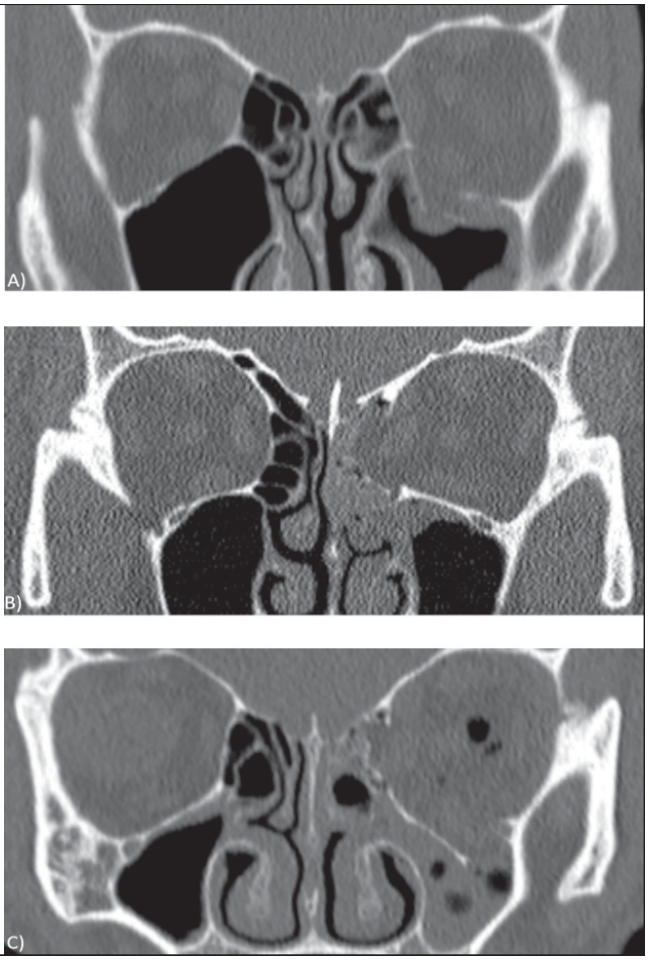



*Figure 8.*
*A) Inferior BOF in left orbit,*

*B) Medial BOF in left orbit,*

*C) Inferomedial BOF in left orbit. These fractures are also open door type fractures.*

Orbital wall fracture can also be described as trapdoor (figure 9) or open door (figure 8) fractures [24]. Entrapment of periorbital contents causing ocular motility restriction, may appear in a trapdoor fracture, where entrapment refers to the soft tissues and the trapdoor to the type of bony injury. In an open door fracture with a clinically verified ocular motility restriction, an impingement of the periorbital tissue would explain the prevention of normal eye movements (figure 10).


*Figure 9.*
*CT scan*

*(A) of a patient with left orbital wall fracture, with clinically limitation to elevate the left eye*

*(B). This patient was considered to have entrapment of the left inferior rectus muscle in a trapdoor fracture.*

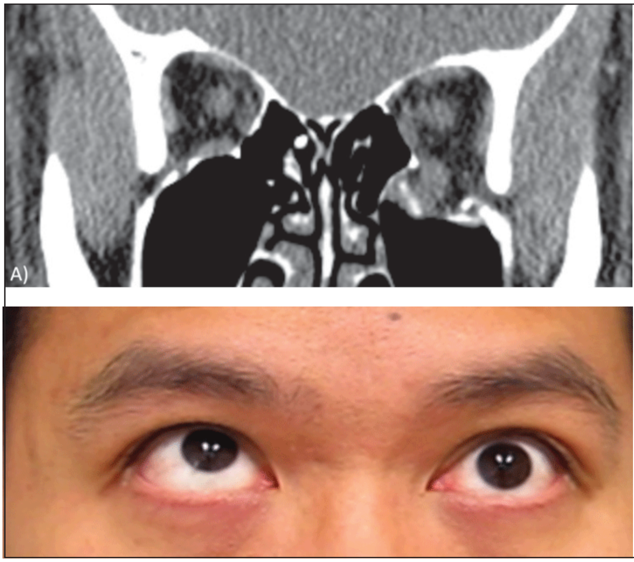



*Figure 10.*
*CT scan*

*(A) of a patient with BOF in left orbit with clinically limitation to elevate the left eye*

*(B). This patient was considered to have impingement of left inferior rectus muscle in an open door fracture.*

# MECHANISM OF FRACTURE

There are two primary theories in how a BOF occurs (figure 11). The *hydraulic theory*, that a traumatic force is transmitted through the eye to the orbital wall resulting in a fracture [25]. The *buckling theory* that a transmission of force from orbital rim, that does not fracture, to the thinner orbital wall that fractures [26]. However, a combination of these two mechanisms is also described by other authors [27].

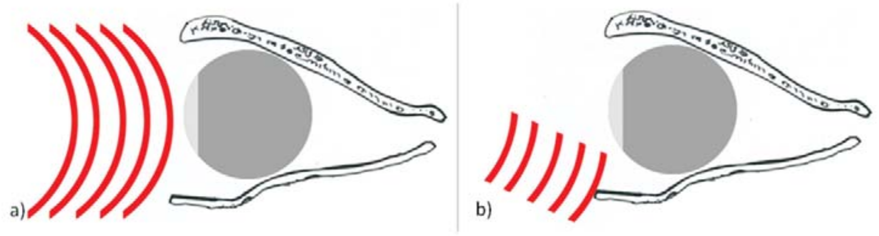



*Figure 11. Theories of mechanism of BOF. a) Hydrolic theory. b) Buckling theory.*

*Figure 12. The examination of the eye by using 2 Q-tips which are rolled inwards to roll a way the eyelids.*

## EYE EXAMINATION

Blindness associated with BOF has been reported in the range of 0.7%-10% [28, 29]. A promptly done eye examination is of outmost priority to limit the risk of vision loss. An ophthalmologic consultation on all patients with BOF is recommended [30]. It is mandatory to examine the visual acuity, papillary response, and fundoscopy. One should always examine the orbit looking for ocular motility limitation [19]. Studies have shown that severe traumatic ocular injuries associated to BOF are not common. Minor ocular injuries associated to BOF can be found up to 30%, but traumatic optic neuropathy in only 3% [31-33].

**CLINICAL FINDINGS**
Hypesthesia of the infraorbital nerve is the most common finding in BOF. Another common finding in BOF is periorbital emphysema after blowing the nose which should be avoided because of risk for orbital compartment syndrome and blindness [34]. Periorbital hematoma occurs frequently in the acute faze and can complicate examination of the eye. But, *no eye is to too swollen to be examined!* Accurate eye examination including the ocular motility is mandatory. By using Q-tips, the swollen eyelids can easily be rolled away and the eye can be examined (figure 12). This maneuver should not cause any pain to the patient.

Almost all the patients with BOF report diplopia due to intraorbital edema, but it is important to exclude that the diplopia is not caused by muscle impingement or entrapment. A useful way to evaluate incarceration of the orbital muscle is forced duction test. This test is uncomfortable for the patient when performed under local anesthesia and therefore usually performed under general anesthesia. Ecchymosis and periorbital hematoma are non-specific findings in BOF.

## IMAGING

CT scan is the gold standard for detecting and evaluating orbital wall fractures. A scan of the facial skeleton including the neck with thin slices (< 2 mm), coronal, sagittal and axial reconstruction in a bone window and a 3D rendering is to be recommended. The inferior orbital wall (floor) is best visualized in coronal view. A sagittal view is ideal to evaluate measurements of how close the fracture reaches to the optic canal and the degree of depression of the orbital floor. The medial wall fractures are best observed on axial view. Although a soft tissue window can be used to evaluate the probability of ocular muscle impingement or incarceration, entrapment of orbital soft tissue can be underestimated [35]. Therefore, an ocular motility limitation is in first hand a clinical diagnosis and not radiologic.

## SURGICAL INDICATIONS

There is currently no consensus on which patients with BOF require surgical intervention and repair [36]. Bony orbital reconstruction has been studied extensively, while the soft tissue injury still needs to be clarified [2]. However, the recommendations in the literature consider absolute and relative indications.

### ABSOLUTE INDICATIONS

Retrobulbar hematoma with compression of the optic nerve or the globe in combination with impaired vision is considered to be an absolute indication for urgent surgery. Optic neuropathy occurs due to increase in intraocular pressure leading to ischemia of the anterior optic nerve [37]. In such a case a lateral canthotomy followed by inferior cantholysis in local anesthesia and then urgent evacuation of the hematoma is necessary [38, 39]. A characteristic sign of retrobulbar hematoma on CT scan is called Martini glas, (figure 13).

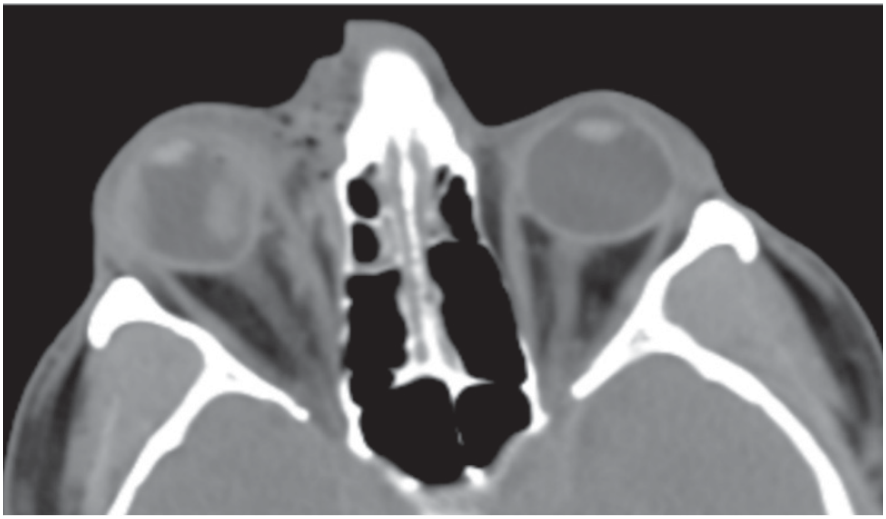


*Figure 13. Sign of Martini glas on the right orbit.*

Intraorbital muscle entrapment may cause oculocardiac reflex. The patient will then suffer from bradycardia, syncope, nausea, vomiting and even asystole. In such a case, immediate surgery is indicated to release the entrapped orbital tissue. Entrapment of the rectus muscle with oculocardiac reflex is more frequently seen in children [40-42]. An entrapment of rectus muscle in a drap door fracture causes limitation in ocular motility. An incarcerated ocular muscle leads to ischemia and if not released immediately, fibrosis and permanent diplopia may develop [43]. This condition can also be called white-eyed BOF [44] when there is no ecchymosis (figure 10 B). A radiologic finding on entrapment is, the missing muscle syndrome (figure 14), when the rectus inferior muscle is not within the orbit but in maxillary sinus [45]. However, the timing of surgical intervention in these patients is not properly studied.

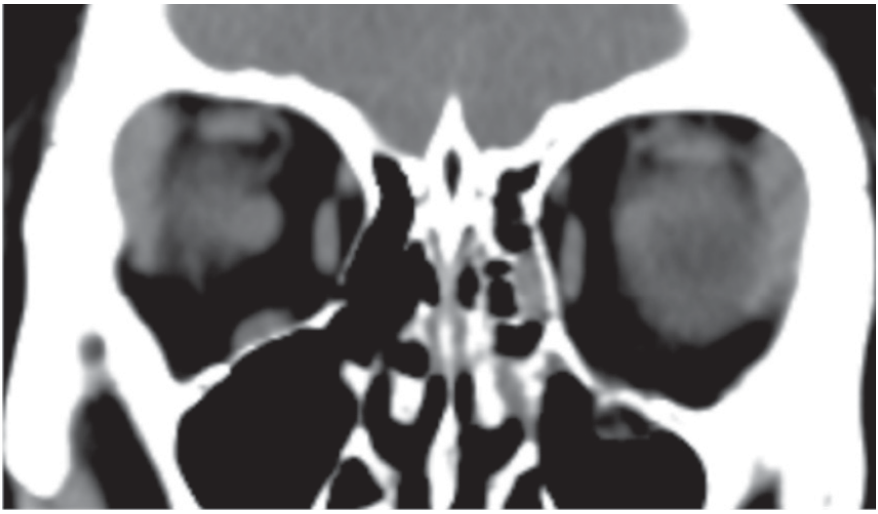


*Figure 14. The missing muscle syndrome. Rectus inferior on the left side is missing.*

An acute enophthalmus and/or hypoglobus in a patient with recent orbital trauma, symbolizes a very large orbital fracture in need of reconstruction after conforming with a CT scan, is also argued to be an absolute indication for surgery by some authors [46].

## RELATIVE INDICATIONS

Not all BOF are considered to need surgical treatment. Most authors recommend surgery in patients with a potential risk for late diplopia [47] and visible deformities such as: enophthalmus (figure 15A), hypoglobus (figure 15B) and superior sulcus deformity (figure 15C) [1,48].

Almost all of the patients with BOF have diplopia which often improves within 2 weeks after the injury [34]. Persistent diplopia with no ocular motility limitation has been suggested as a surgical indication in BOF [46], while other authors have reported spontaneous recovery of diplopia 1 year after injury [49].

It is reported that the outcome of late correction of BOF is not optimal compared to early correction. Therefore early surgery before the deformity appears has been advocated [38, 50]. Due to this, it has been considered important to identify patients in risk zone of developing late symptoms in advance and perform surgical correction. During the last decades findings on CT scans have been used to predict the potential risk for late aesthetic deformities. Earlier studies have shown that changes in the orbital volume may lead to orbital contour deformity [51-53]. The cut-off points between surgical and non-surgical treatment have been recommended at; >1.5 ml herniation [53], increase in cranial- caudal dimension of the orbit > 0.8 cm [54], an orbital floor fracture >1 $cm^2$ [55], >50% fractured orbital floor [50], diplopia 2 weeks after the trauma [50] or an enophthalmus greater than 2 mm acute or after 6 weeks [55]. A BOF involving both the inferior and medial walls has been shown to be associated with higher risk for late enophthalmus [56].

It has become obvious that not only the amount of herniated orbital tissue, but other findings such as the area and location of the fracture are important factors to consider when predicting late sequelae.

It is crucial to differentiate which BOF require surgical treatment with a high accuracy, since surgical complications have been reported to be up to 20% [57, 58].

**RELATIVE CONTRAINDICATIONS**

Any condition that adventures the vision can be a contraindication to surgical intervention. Elderly patients with mild or serious physical illnesses may live with some degree of orbital deformity rather than the risks anesthesia may cause. Surgery in a patient´s only seeing eye can be necessary if the indication is ocular motility limitation, but not preventing from orbital contour deformity. Furthermore, orbital repair of a patient who has hyphema or a lacerated globe would put the vision in a high risk. Therefore, an ophthalmologist consultation is of high value. Other ophthalmologic findings such as traumatic iritis, traumatic mydriasis and commotio retinae do not prevent a BOF reconstruction, if needed [47].


*Figure 15) A) Left eye, 3 mm enophthalmus, B) Right eye, hypoglobus but no enophthalmus, C) Left eye, superior sulcus deformity and 2 mm enophthalmus.*

## TIMING OF TREATMENT

There are controversies about the timing of surgery as the surgical indications. There are reports that early surgery (within 2 weeks) have better outcome compared to late reconstruction (2-3 months) [50, 59], while other authors suggest more conservative approach [1]. However, with a delay the periorbital edema decreases which is beneficial for new examination or surgical intervention.

### IMMEDIATE REPAIR

In case of oculocardiac syndrome or retrobulbar hematoma with progressive impairment/lose of the vision, an urgent intervention is mandatory. To avoid blindness a decompression within 2 hours of the once of the symptom has been stated [60]. In a case of ocular motility limitation, especially in children, surgical intervention within hours to release the impinged or incarnated ocular muscle or tissue is well recognized [38, 47].

### WITHIN TWO WEEKS

When there is no urgency but substantial risk for late visible deformity surgical reconstruction within 2 weeks is recommended [38]. Same timeframe is applicable for the patients who have developed visible deformity, either acute or late. However, the current guidelines are insufficient to support the best timing for non-urgent orbital repair [61].

## SURGICAL MANAGEMENT

### APPROACH

Several incisions are described to approach to orbital floor (figure 16). Complication to the incision such as scleral show and ectropion are more associated with the subciliary incision. Transconjuctival incision is associated with entropion, but it has low rate of complication compare to the other incisions [58]. However, the difference between the pre- and retro transconjuctival has not been studied. Furthermore, there is a lack of established follow up time interval to evaluate and compare the severity of complications [58].

There are many approaches to repair the medial orbital wall such as: transcutaneous (Lynch incision), transconjuctival inferior fornix, transcaruncular and endoscopic trans-ethmoidal. Nowadays surgeons prefer transcaruncular approach, since it can easily be combined with transconjuctival approach [34].

BOF can be repaired endoscopicly through transantral or endonasal approach [62, 63]. This technique is excellent in case of entrapment of ocular muscle and hyphema when orbital retraction is potential risk for blindness. Endoscopic release of the entrapped muscle can be achieved without retracting the eye. Also the risks for eyelid malposition cause by an incision are excluded [64].

### SURGICAL TECHNIQUE

A surgical procedure should always start with evaluating the ocular mobility by a bilateral forced duction test. The orbit is approached by one of the described incisions, preferably transconjuctival incision for the inferior wall, transcaruncular incision for the medial wall and a combination of these two for the inferomedial wall repair.

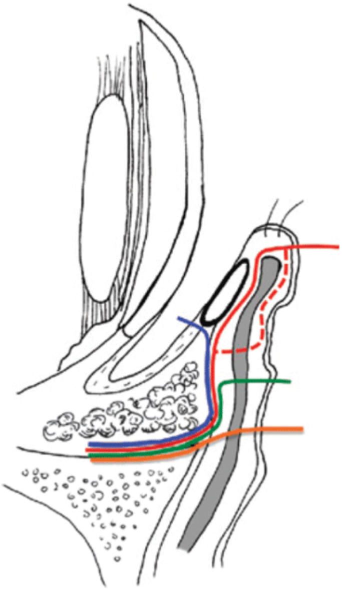


*Figure 16.*
*Sagittal viem of incisions for orbital floor exploration.*

*Solid red=non-stepped subciliary,*

*dotted red=subcilisry stepped,*

*blue=transponjuctival,*

*green=subtrasal and*

*orange=infraorbital.*

*Fig. origin:Kothari et al. Incisions for orbital floor explorations [58].*

Once one reaches the bone a subperiosteal dissection in performed. Orbital tissue is elevated, preferably by a malleable retractor until the anterior edge of the fractured is identified. Avoid pulling the herniated orbital tissue which is usually anchored to the depressed orbital wall. A dissection along the intact bony edges of the fracture, for instance, first lateral and then medial to the fracture. To get better exposure of the orbital floor, the tissue in the inferior orbital fissure is cauterized and cut. This will give much more visibility. The infraorbital nerve just medial to the inferior orbital fissure and usually involved in the fracture should always be identified. Any segment of bone limiting the retraction of herniated orbital tissue can be removed.

The herniated orbital tissue is separated subperiostealy along the surface of the displaced orbital wall, starting not necessarily anteriorly, but where ever it is easier accessed. If any periorbital tissue is attached to the infraorbital nerve it is released until the posterior aspect of the inferior orbital fissure. The infraorbital nerve is left in the maxillary sinus and everything above the nerve stays in orbit. Continue the dissection until the ring of the fracture and the posterior ledge is identified.

The implanted is sized and shaped as a “lazy-S” and placed over the entire defect so all the edges rest on the bone and fixed. It is important to restore the orbital anatomy to the pretrauma shape.

In a trapdoor fracture orbital tissue can be pinched in the orbital floor. It is important not to pull the incarcerated tissue. Instead, the trapdoor should be pushed down or the fracture can be made larger to lift out the tissue.

Intraoperative verification of the adequacy of the reconstruction is recommended with either CT scan or navigation [47].

**IMPLANT SELECTION**

It has been a regime shift from earlier usage of autogenous material to alloplasts material with the improvement in the material it has gone through the last years. Bone can easily be fixed, radiographed, has good strength and no sharp edges but its resorption and abscens of elasticness creates limitation [65]. Because of low accuracy in orbital volume restoring and reconstruction of shape and potential donor site morbidity, is it not recommended using it as primary [66].

Reconstruction with septal and auricular cartilage has been reported [67]. Compared to the other implants, titanium mesh is considered highly biocompatible, good strength, easily adjusted to fit simple and complex orbital defects and readily available. Its drawbacks are the sharp edges which can hook up in the orbital tissue when inserting and holes in the plate through which tissue grows in and make the removal difficult [65, 66]. Porous polyethylene in addition to all the advantages as titanium, can be easily removed if needed but it is not radiopague. However, there are radiologically visible titanium reinforced porous polyethylene sheets [65]. Resorbable implants have been used for orbital repair but there has been a concern about loss of long-term support [65]. In inferomedial wall fractures preformed mesh implant is preferable compared to patient specific implant and freehand bended titanium mash [69].

Patient-specific implants are the latest commercialized material in the field. These implants are anatomically ideal to achieve more accurate reconstruction and reduce operative time [68]. Computer-aided surgery is the latest tool for surgeons to improve the orbital reconstruction accuracy significantly [2]. These two fields are believed to develop more in future.

**POSTOPERATIVE CARE**

Once the patient is sufficiently awake at the recovery room basic visual acuity and ocular motility should be checked. This has to be repeated once every hour within the first 6 hours [47]. The head should be kept elevated to decrease the postoperative edema. The next 2 weeks postopertively, the patient should avoid blowing their nose and heavy lifts. The patient should be informed to expect priorbital edema and pain, up to several weeks of slowly decreasing diplopia and instructed regarding symptoms of retrobulbar hematoma.

## COMPLICATIONS

Loss of vision after orbital reconstruction is mostly related to intraorbital bleeding and is fortunately rare (0.4%) [70]. Although, the post-operative diplopia is transient [47], 7%-37% a persistent diplopia are reported [71, 72]. This is believed to be cause by fibrosis or trauma to nerve or muscle [73]. Not improving postoperative diplopia or ocular motility disorder can also be caused by a mal-placed implant. The incidence of postoperative enophthalmus is reported to 7% by Hosal et al [72]. Scaring in the lower eyelid resulting in scleral show, en- or ectropion are other known post-surgical complication mostly associated with to the type of the incision

# AIMS

## AIMS OF THE THESIS

The main aim of this thesis was to identify which patients with orbital BOF are in need of surgical treatment due to early as well as late functional and aesthetic disorders.

**PAPER I**

- To study whether the decision to refrain from surgery based on the herniated volume of < 1.5 ml in a series of patients was correct.
- To investigate whether the relative change in the orbital volume would be a better indicator for surgical versus nonsurgical treatment of BOF.

**PAPER II**

- To study the differences in opinion between the specialties and surgeons from different countries in managing BOF.
- To determine if surgeons handle BOF cases based on their own individual criteria.

**PAPER III**

- To evaluate the importance of the time from injury to surgery in relation to outcomes in ocular motility and diplopia.
- To study the time line for ocular motility and diplopia recovery.
- To study the degree of and recovery from hypesthesia.

**PAPER IV AND V**

- To evaluate which patients with BOF develop functional and cosmetic problems.
- To investigate which CT scan findings can be used to predict late visible deformity in patients with BOF with non-surgical treatment.
- To investigate which patients with BOF benefit from surgical vs nonsurgical treatment.
- To provide an algorithm based on available evidence to predict which patients with BOF benefit from surgical vs nonsurgical treatment.
- To evaluate the importance of timing for surgical repair.

# MATERIAL AND METHODS

All the papers I-V were approved by the Ethics Committee of the Karolinska Institutet (EPN) Stockholm, Sweden and the study protocols and informed consent were obtained from each individual included in the studies. The author is the photographer of all the pictures on patients. The patients have given their written permission for publication of their picture.

## PAPER I

Patients with non-surgically treated unilateral BOF based on the herniated orbital volume < 1.0-1.5 ml between 2003-2007, were selected. 89 patients met the criteria. They all were contacted and invited to the clinical eye examination. 43 patients responded to the letter. 20 patients were excluded as follow: 2 had isolated medial wall fracture, 12 had been scanned with CT slices thicker than 2 mm, which worsened detail resolution in the analysis, 6 individuals did not show up for examination. 23 patients were included in the study (19 men, 4 women).
The volumes of the orbital content bilaterally were calculated digitally from the CT scans at the time of their injury. The volume of the herniation (figure 17) and the volume of the orbit including the herniation (figure 18) were measured.

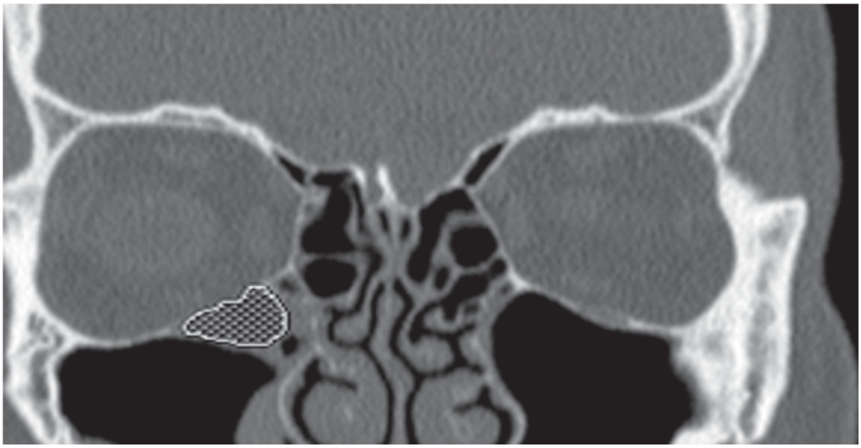


*Figure 17. The volume of the herniated orbital content.*

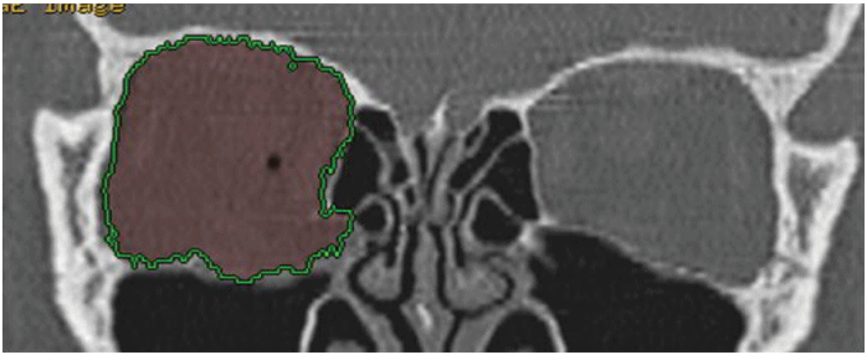


*Figure 18. Volume of the orbital content including the herniated orbital volume.*

The orbital volume of the non-fractured side was also measured for calculating the relative volume difference. Orbital volumes of 18 patients with no facial trauma were measured as controls. These measurements were used to estimate the individual variability of orbital volumes in normal individuals. To facilitate repetitive volume measurements, a standardized method of defining the orbital borders was created by defining three distinct anatomic landmarks on the CT scan.

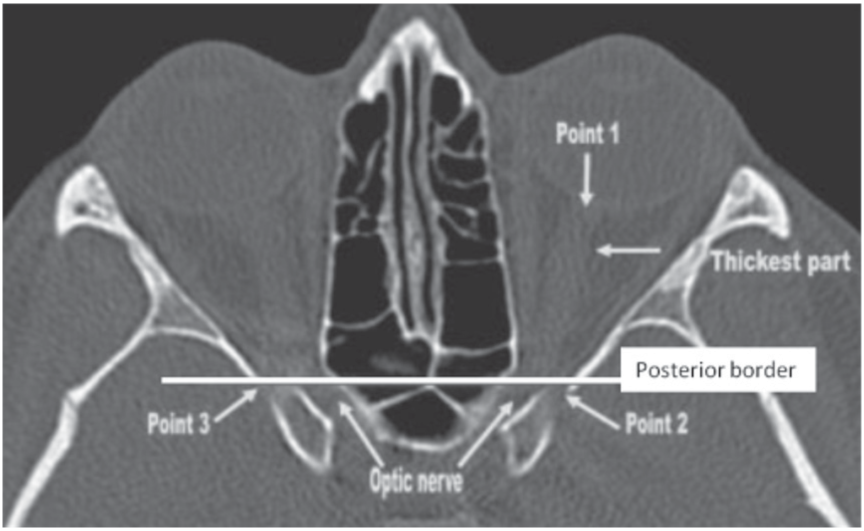



*Figure 19. The posterior border in orbital volume measurements. Point 1, the exit of the optic nerve from the eye globe. Points 2 and 3 are the lateral edges of the superior orbital fissure on each side.*

These were: (1) posterior—in the central portion of the optic nerve at the level of the lateral edge of the superior orbital fissure (figure 19); (2) anterior/nasal—the most distinct and widest laterodorsal duct of the lacrimal canal bilaterally; (3) anterior/temporal—the most anterior portion of the lateral orbital limit (figure 20). The volume of the orbit was calculated craniocaudally inside the bony orbital borders within these three points using software in the Volume Viewer version 2.0 (GE Healthcare). See Appendix for details.

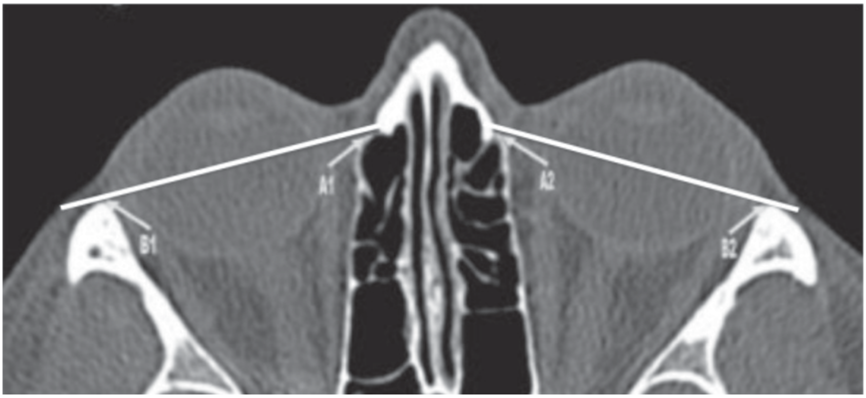



*Figure 20. The anterior border in the orbital volume measurements. A1 and A2, the most distinct and widest laterodorsal duct of the lacrimal canal; B1 and B2, the lateral orbit limits.*

The localization of the fracture was measured on the sagittal CT slice where the fracture was considered largest. The distance from the infraorbital rim to the anterior and the posterior part of the fracture was measured (figure 21).

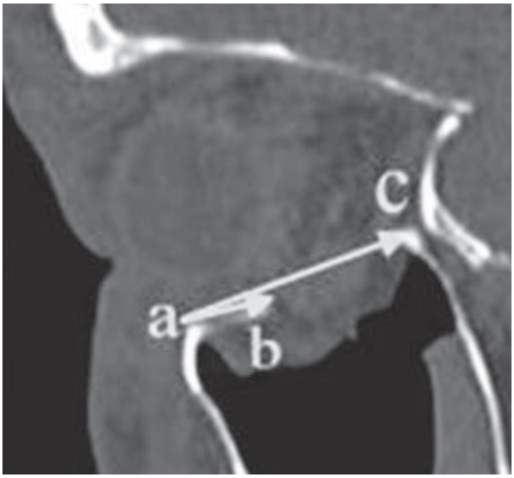



*Figure 21.*
*Sagittal computed tomography slice where the fracture is considered largest.*

*(A) Infraorbital margin,*

*(B) anterior, and*

*(C) the posterior part of the fracture.*

# PAPER II

From the patient records, 11 cases with BOF were selected. Eight patients had been treated non-surgically and three patients surgically. Patients were contacted and invited to a clinical eye examination. The patients were controlled for the diplopia, enophthalmus and they reported the presence of double vision. At the time of injury the patients had a mean age of 30 years (13–62). At the first visit after the injury two patients (cases 6 and 9) had diplopia, nine patients (cases 1, 2, 3, 4, 5, 7, 9, 10, and 11) had no diplopia according the chart review. A power point presentation of each patient was prepared, based on summaries of the patients' first visit to the hospital including history and symptoms, findings on examination, the result of ophthalmologic examination and CT scan slices of the fracture area, both in coronal and sagittal projections. The 11 cases were presented to a total of 46 surgeons involved in orbital floor fracture management. Surgeons from different specialities and countries were recruited from centers of excellence in trauma care. The specialities and countries of origin are presented in figure 22.

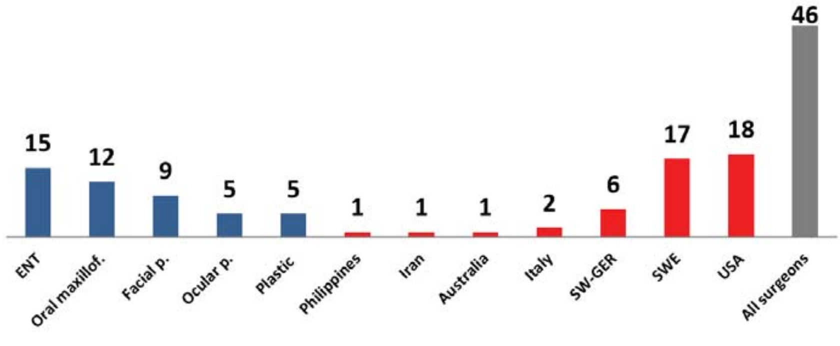



*Figure 22. The surgeons´speciality and country of origin.*

The surgeons were asked to give their opinions as to whether surgery was necessary or not, the timing of the surgery and the risk for late enophthalmus. For subgroup analysis the participating surgeons were subdivided according to specialty and country of origin. The responses from the subgroups were compared. We considered the surgeons in a group to be ''in agreement'' if there was 75% agreement on whether or not to operate, when to operate or on the risk for late enophthalmus. In analyses including all eleven patients, percent of overall agreement over all pairs of raters and kappa (k) measure of agreement are provided. A rule of thumb is that a k of 0.70 or above indicates adequate interrater agreement. Randolph, J.J. (2008). Online Kappa Calculator. Retrieved from http://justus.randolph.name/kappa (June 7, 2012).

## PAPER III, IV AND V

These were prospective studies of patients with CT scan verified unilateral isolated inferior, inferomedial or medial orbital wall fracture, performed at the Department of Otorhinolaryngology and Head & Neck Surgery at the Karolinska University Hospital in Stockholm, Sweden, between 2011 and 2016. After clinical examination and evaluation of the CT scans, patients were asked to participate in this project.

Patients with acute ocular motility restriction due to entrapment (figure 9) or impingement (figure 10) of orbital contents were included to an observational study. Patients were treated according to current guidelines with urgent to early surgical intervention to release the affected ocular muscle and if needed a reconstruction of the orbital walls. A forced duction test [74] was performed under general anesthesia prior and at the end of the surgery in order to determine whether ocular motility restriction was present or not. The results are published in paper III in this project.

Patients who were not assessed to benefit from surgical intervention according to current guidelines at the Karolinska University Hospital, were included to an observational study (non-operated and operated) and the results are published in paper IV in this project. The guidelines at Karolinska University hospital in BOF are surgical treatment if a herniation >1.5 ml, due to risk for late enophthalmus and the decision is taken by a consultant.

Patients with ≥ 1.0 ml herniation were included in a controlled randomized pilot study. Patients were randomized to observational or surgical treatment. The results are published in paper V in this project.

After the inclusion, patients were followed for a minimum of one year with up to five clinical examinations. At each visit, patients completed a self-reported questionnaire (Appendix 1) and a clinical examination was performed by a physician (Appendix 2) for functional symptoms such as ocular motility, diplopia, hypesthesia of the infraorbital nerve, as well as cosmetic deformities such as enophthalmus, hypoglobus and superior sulcus deformity. The measurement of enophthalmus was performed using a Hertel ophthalmometry [75]. Hypoglobus and superior sulcus deformity were noted if they were visible.

If a patient developed symptoms in need of surgical correction i.e. persisting diplopia or visible deformity, surgery was offered. Surgically treated patients

*Table 1. Patients with inferior wall, inferomedial wall and medial wall fracture with visible vs no visible deformity in comparison with CT scan measurements. ROC curve results (area under the curve) and cut-off points. a Calculated with Wilcoxon test, b Calculated with Fisher's exac t test. Paper IV.*

| | Inferior wall fractures (n=54) | | | | Inferior wall fracture with < 1.0 ml herniation (n=28) | | | | Inferior wall fracture with ≥ 1.0 ml herniation (n=26) | | | | Inferomedial wall fracture (n=18) | | | | Medial wall fracture (n=7) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CT-scan measurements | A) No Visible Deformity (n=38) | B) Visible Deformity (n=16) | P value A vs B | AUC/ (Cut-off point) | C) No Visible Deformity (n=24) | D) Visible Deformity (n=4) | P value C vs D | AUC)/ (Cut-off point) | E) No visible Deformity (n=14) | F) Visible Deformity (n=12) | P value E vs F | AUC/ (Cu- off point) | G) No Visible Deformity (n=7) | H) Visible Deformity (n=11) | P value G vs H | AUC/ (Cut-off point) | I) No Visible Deformity (n=5) | J) Visible Deformity (n=2) | P value I vs J |
| Inferior orbital rim to the anterior edge of the fracture (cm) | 0.8 (0.29-1.7) | 0.8 (0.1-1-6) | 0.834[a] | 0.52 | 0.95 (0.3-1.8) | 0.65 (0.1-1.5) | 0.307[a] | 0.66 | 0.4 (0.3-1.5) | 0.8 (0-2-1.6) | 0.097[a] | 0.69 | 1 (0.1-1.5) | 0.6 (0.2-1.2) | 0.927[a] | 0.51 | 0,6 (0.3-1.2) | 1.4 (1.3-1.5) | 0.052[a] |
| Inferior orbital rim to the posterior edge of the fracture (cm) | 2.8 (2.2-3.1) | 3.1 (2.3-3.4) | 0.009[a] | 0.72 | 2.7 (2.1-3.2) | 2.9 ( 2.4-3.3) | 0.390[a] | 0.64 | 2.9 (2.6-3.1) | 3.1 (2.2-3.5) | 0.025[a] | 0.75 (3.0 cm) | 2.9 (1.8-3-3) | 3.1 (2.0-3.5) | 0.202[a] | 0.68 | 3 (2.4-3.6) | 3.6 (3.4-3.8) | 0.121[a] |
| Length of the fracture (cm) | 1.9 (1.1-2.6) | 2.3 (1.5-2.6) | 0.051[a] | 0.67 | 1.7 (1.0-2.5) | 2.2 (1.8-2.3) | 0.052[a] | 0.65 | 2.4 (1.5-2.8) | 2.4 (1.1-2.6) | 0.815[a] | 0.52 | 1.8 (0.8-2.8) | 2.4 (1.3-3.0) | 0.317[a] | 0.64 | 2.1 (1.8-3.0) | 2.2 (2.1-2.3) | 0.845[a] |
| Displacement of orbital bulge (mm) | 3.0 (0-7.7) | 3.2 (0-11.0) | 0.717[a] | 0.53 | 2.9 (0-6.5) | 1.4 (0-5.4) | 0.409[a] | 0.63 | 3.4 (0-11.3) | 3.7 (0-12.7) | 0.816[a] | 0.53 | 1.9 (0-7.4) | 3.4 (0-5.7) | 0.412[a] | 0.62 | 0 | 0 | |
| Dislocated fracture in medial buttress i=No, ii=Yes (n) | 36[i], 2[ii] | 15[i], 1[ii] | 0.885[b] | | 22[i], 2[ii] | 4[i], 0[ii] | 0.423[b] | | 14[i], 0[ii] | 11[i], 1[ii] | 0.270[b] | | 5[i], 2[ii] | 5[i], 6[ii] | 0.274[b] | | 0 | 0 | |
| Width of Fracture (cm) | 1.4 (0.9-2.0) | 1.7 (1.1-1.9) | 0.044[a] | 0,67 | 1.3 (0.8-1.6) | 1.4 (1.1-2.0) | 0.528[a] | 0.59 | 1.7 (1.3-2.3) | 1.7 (1.2-1.9) | 0.979[a] | 0.50 | 1.8 (1.2-2.1) | 1.8 (1.2-2.5) | 0.715[a] | 0.61 | 1.3 (1-1.8) | 1.1 (1.0-1.2) | 0.167[a] |
| Ratio between the largest width of the fracture and the total width of the fractured orbital wall (%) | 59 (35-82) | 71 (42-90) | 0.016[a] | 0.71 | 55 (32-70) | 63 (44-71) | 0.340[a] | 0.65 | 68 (56-87) | 77 (46-96) | 0.571[a] | 0.57 | 67 (50-100) | 74 (53-96) | 0.927[a] | 0.48 | 72 (68-100) | 69 (67-70) | 0.118[a] |
| Area of the fracture ($cm^2$) | 2.1 (1.2-3.5) | 2.7 (1.5-3.5) | 0.048[a] | 0.67 | 1.7 (1.1-2.5) | 2.3 (1.9-2.6) | 0.048[a] | 0.81 (2.3 $cm^2$) | 3.1 (1.7-4.3) | 3.0 (1.5-3.7) | 0.425[a] | 0.59 | 3.6 (0.9-4.4) | 5.0 (3.0-6.9) | 0.020[a] | 0.84 (4.8 $cm^2$) | 2.7 (1.2-3.7) | 2.6 (2.0-3.1) | 0.698[a] |
| Ratio between fracture and the fractured orbital wall areas (%) | 37 (20-62) | 47 (28-61) | 0.038[a] | 0.68 | 32 (19-40) | 42 (31-43) | 0.035[a] | 0.83 (42%) | 52 (31-74) | 51 (24-63) | 0.503[a] | 0.58 | 39 (8-45) | 44 (33-60) | 0.063[a] | 0.76 | 53 (22-58) | 52 (42-62) | 0.438[a] |
| Volume of the herniated orbital tissue (mL) | 0.9 (0.3-1.7) | 1.3 (0.7-2.7) | 0.001[a] | 0.77 (1.0m) | 0.66 (0.2-1.0) | 0.8 (0.6-1.0) | 0.189[a] | 0.65 | 1.4 (1.0-2.5) | 1.9 (1.1-2.9) | 0.149[a] | 0.67 | 0.7 (0.4-0.9) | 1.5 (0.8-2.6) | 0.0007[a] | 0.98 (0.9 ml) | 0.8 (0.3-2.0) | 1.2 (0.8-1.6) | 0.438[a] |

*Table 2. Patients with inferior and inferomedial Orbital BOF, randomized to observation and surgery and subgroups with visible vs no visible deformity in comparison with CT scan measurements. a Calculated with Wilcoxon test, b Calculated with Fisher's exact test. VD = Visible deformity, No VD = No visible deformity. Paper V.*

| CT-scan measurements | Observational (n=10) (A) | Surgical (n=16) (B) | P value A vs B | Observational (n=6) VD (C) | Observational (n=4) No VD (D) | P value C vs D | Observational (n=1) inferior VD (E) | Observational (n=4) inferior VD (F) | P value E vs F |
|---|---|---|---|---|---|---|---|---|---|
| **Inferior orbital rim to the anterior edge of the fracture (cm)** | 0.6 (0.3-1.5) | 0.9 (0.5-1.6) | 0.22 $^a$ | 0.5 (0.4-0.7) | 1.2 (0.3-1.6) | 0.20 $^a$ | 0.4 | 1.2 (0.3-1.6) | 0.72 $^a$ |
| **Inferior orbital rim to the posterior edge of the fracture (cm)** | 3.0 (2.7-3.5) | 3.3 (2.6-3.6) | 0.13 $^a$ | 3.1 (2.9-3.3) | 2.9 (2.7-3.5) | 0.19 $^a$ | 3.3 | 2.9 (2.7-3.5) | 0.46 $^a$ |
| **Length of the fracture (cm)** | 2.5 (1.6-2.9) | 2.2 (1.6-3.0) | 0.69 $^a$ | 2.6 (2.3-2.9) | 1.8 (1.6-2.5) | *0.02* $^a$ | 2.9 | 1.8 (1.5-2.5) | 0.15 $^a$ |
| **Displacement of orbital bulge (mm)** | 3.4 (1.3-7.9) | 4.2 (0-9.8) | 0.71 $^a$ | 3.1 (1.2-6.6) | 4.8 (1.7-8.1) | 0.45 $^a$ | 2.5 | 4.8 (1.7-8.1) | 0.47 $^a$ |
| **Dislocated fracture in inferomedial buttress i=No, ii=Yes (n)** | $6^{i}$, $4^{ii}$ | $12^{i}$, $4^{ii}$ | 0.42 $^b$ | $2^{i}$, $4^{ii}$ | $4^{i}$, $0^{ii}$ | *0.04* $^b$ | $1^{i}$, $0^{ii}$ | $4^{i}$, $0^{ii}$ | 0 $^b$ |
| **Width of Fracture (cm)** | 2.0 (1.3-2.3) | 1.7 (1.3-2.2) | 0.56 $^a$ | 2.0 (1.8-2.3) | 1.4 (1.3-1.9) | *0.02* $^a$ | 2.0 | 1.4 (1.3-1-9) | 0.15 $^a$ |
| **Ratio between the largest width of the fracture and the total width of the fractured orbital floor (%)** | 70 (50-87) | 68 (55-89) | 0.46 $^a$ | 82 (69-87) | 61 (52-67) | *0.01* $^a$ | 83 | 61 (52-68) | 0.15 $^a$ |
| **Area of the fracture ($cm^2$)** | 3.9 (1.8-6.9) | 3.4 (1.9-5.4) | 0.56 $^a$ | 4.8 (3.8-7.2) | 2.2 (1.8-2.7) | 0.01 $^a$ | 4.0 | 2.2 (1.8-2.7) | 0.15 $^a$ |
| **Fracture type: i=inferior, ii=inferomedial** | $5^{i}$, $5^{ii}$ | $9^{i}$, $7^{ii}$ | 0.09 $^b$ | $1^{i}$, $5^{ii}$ | $4^{i}$, $0^{ii}$ | *0.003* $^b$ | $1^{i}$, $0^{ii}$ | $4^{i}$, $0^{ii}$ | 0 $^b$ |
| **Volume of the herniated orbital tissue (ml)** | 1.7 (1.3-4.0) | 2.2 (1.3-3.7) | 0.22 $^a$ | 1.8 (1.3-4.2) | 1.4 (1.3-2.9) | 0.21 $^a$ | 1.8 | 1.4 (1.3-2.9) | 0.65 $^a$ |

were followed for at least one year after surgery. Patients were asked if they felt satisfied with the treatment they received at each visit. The patients' questionnaire and the physicians' protocol was study specific and have not been validated.

The CT scans were performed with ≤ 2mm slices, (except in 4 patients with 3 mm slices in paper IV). CT scans of patients in paper IV (table 1) and V (table 2) who completed the study were analyzed for several measurements. They were transferred to a workstation (GE Healthcare Advantage Workstation version 4) where the images were evaluated in axial, coronal and sagittal planes in an osseous window level setting.

## CT SCAN MEASUREMENTS PAPER IV AND V

Measurements were made accordingly: Sagittal plane where the fracture was considered largest in the inferior wall:

i) the distance from the inferior orbital rim to the anterior edge of the fracture (figure 23A$^{i}$); on the same slice
ii) the distance from the inferior orbital rim to the posterior edge of the fracture (figure 23A$^{ii}$);, on the same slice;
iii) the longest antero-posterior length of the fracture (figure 23A$^{iii}$),
iv) the largest degree of displacement of orbital bulge in mm (figure 23B).

Coronal plane:

v) the largest width of the fracture (figure 23C$^{i}$) and the wall (figure 23C$^{ii}$),
vi) the ratio between the largest width of the fracture and the total width of the fractured orbital wall on the same slice;
vii) the area of the fracture (figure 23D), respectively and;
viii) the total area of fractured orbital wall (only paper IV) (figure 23E), respectively, and;
ix) the ratio between fracture and the fractured orbital wall areas (only in paper IV);
x) the volume of the herniated orbital tissue (figure 23F),
xi) in medial wall fractures the supero-inferior extent of the fracture was measured as the width of the fracture (figure 23G$^{i}$) and on the same slice the supero-inferior extent of the total wall (only in paper IV) (figure 23G$^{ii}$),
xii) if the inferomedial buttress was fractured and dislocated (figure 23H).

xiii) In axial plane where the fracture was considered as largest in the medial wall the distance from anterior lacrimal crest to the anterior edge of the fracture (figure 23I$^{i}$); on the same slice (only in paper IV).

xiv) the distance from the anterior lacrimal crest to the posterior edge of the fracture (figure 23I$^{ii}$), on the same slice (only in paper IV);

xv) the longest antero-posterior length of the fracture (figure 23I$^{iii}$) (only in paper IV).

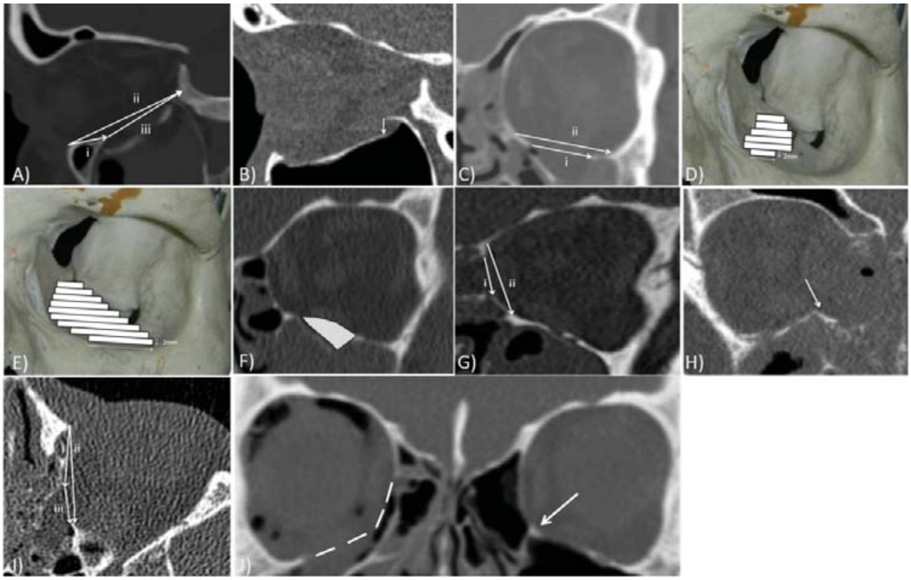



*Figure 23. A) Inf. orbital rim to: -ant. edge of the fx$^{i}$, -post. edge of the fx$^{ii}$ and the longest antero-posterior length of the fx$^{iii}$. B) Displacement of orbital bulge. C) Largest width of the fx$^{i}$ and the orbital floor$^{ii}$. D) Area of the fx. E) Area of the fractured orbital wall. F) Volume of the herniated orbital tissue. G) Supero-inferior extent of the fx$^{i}$ and supero-inferior extent of the wall$^{ii}$. H) Medial buttress fractured and dislocated. I) Ant. lacrimal crest to -ant. edge of the fracture i, -post. edge of the fracture ii and longest antero-posterior length of the fx$^{iii}$. J) Estimation of displaced Inferomedial buttress in comparison with the unfractured contra-lateral orbit and Inferomedial buttress (arrow).*

Patients were categorized into three fracture types depending on which orbital wall was fractured:

1. Inferior wall fracture (medial to the infraorbital nerve and lateral to the inferomedial buttress).
2. Inferomedial wall fracture (both inferior and medial walls).
3. Medial wall fracture (medial to the inferomedial buttress, only in paper IV).

CT scan measurements of patients with visible deformity were compared to patients with no visible deformity within each group (table 1 for paper IV and table 2 for paper V).

*Area and volume measurements*
All measurements were performed using the GE Healthcare Advantage Workstation version 4 (GE Healthcare, Milwaukee, WI).

*Area*
We performed a quantitative computational method for calculating the area of the fractures (paper IV and V) and the walls (only paper IV) [76, 77]. Stacks of 2-mm slices were made in the coronal plane. The width of the inferior or medial orbital wall in each 2 mm-slice was measured. This resulted in trapezoidal strips with a known area (see fig 23E). The areas of the strips were multiplied to calculate the entire area of the wall. In the 4 cases where CT scan was performed with 3 mm slices the same procedure was followed, but instead made with 3 mm stacks. The area measured was based upon the following landmarks: the medial border of the floor by the inferomedial buttress (fig 23J), the lateral border of the floor anteriorly at the point of the highest angle of the zygomatic bone and posteriorly by the medial edge of the inferior orbital fissure. The anterior border of the orbital floor was defined as the first slice that showed a measurable distance of the maxillary sinus. In the medial wall the starting point was the posterior lacrimal ridge and ending at the anterior sphenoidal wall. The cranio-caudal distance was measured between the inferomedial buttress and the ethmoido-frontal suture. Where the inferomedial buttress was displaced the measurement was estimated after comparison with the unfractured contra-lateral orbit (Figure 23J).

*Volume*
The CT scans used were preferably axial raw thin slices in a soft tissue window setting (HU 600/1000) to distinguish blood from orbital fat and muscle tissue. The superior or lateral border (in medial fractures) was estimated. The contralateral orbit was used as a reference. Starting with the coronal plane

the first slice that showed the fracture was chosen. The following steps were taken: “VR tools”; “Segment”; “Quick paint” with brush size 2 mm. The herniated content was marked green in one slice and then scrolled 2-3 steps posteriorly to mark the content again. In case of 2-3 mm slices only one step at a time was scrolled. This was repeated until all the content was marked in this plane. Then the same procedure was performed in the sagittal plane to fill in the gaps between the coronal slices. In the medial fractures the coronal and axial planes were used instead. The marked area was applied and the “Display tools” were used. The “Threshold” was set between -300 and 200 to exclude bone and air. To measure volume the “Globe” function was used.

## STATISTICAL ANALYSES

Different set of quotative methods and statistical approaches were utilized when analyzing data involved within this work across the papers; for which the theoretical and practical aspect of the methods have been highlighted within each paper. Here briefly some of the methods and software’s used for their implementation are summarized.

### PAPER I

The data were analyzed with the StatSoft, Inc. (2007), Statistica (Dell software system), version 8.0 (www.statsoft.com). A correlation analysis was performed on the orbit measurements and the ophthalmologic data to determine the coefficient of determination ($r^2$). To evaluate the reproducibility of the measured orbital volumes, two people separately calculated the orbital volumes using the same method. The intraclass correlation coefficient (ICC) was derived from a two-way mixed-effects model.

### PAPER II

The kappa analysis performed for the participating surgeons were according to specialty and country of origin. We considered 75% agreement on whether to operate, when to operate or on the risk for late enophthalmus. In analyses including all eleven patients, percent of overall agreement over all pairs of raters and kappa (k) measure of agreement are provided. A rule of thumb is that a k of 0.70 or above indicates adequate interrater agreement. Randolph, J.J. (2008). Online Kappa Calculator. Retrieved from http://justus.randolph.name/kappa (June 7, 2012).

### PAPER III, IV AND V

All continuous variables are expressed as median (10th and 90th percentile) and nominal variables as percentages, as appropriate. Statistical significance was set at the level of $p<0.05$. Comparisons between two groups were assessed with the non-parametric Wilcoxon test for continuous variables and Fischer exact test or Chi square test for nominal variables. Differences between three or more groups were analyzed with Kruskal Wallis test followed by Dunn´s test. Receiver operating characteristics (ROC) derived area under the curve (AUC) values were used as cut-offs for statistical analyses followed by multinomial logistic regression analysis. All statistical analyses were performed using statistical software SAS version 9.4 (SAS Campus Drive, Cary, NC, USA).

*Table 3. Summary of the clinical and CT scan findings in paper I.*

| Patient | Diplopia | Note to Diplopia | Enophthalmos (mm) | Herniated Volume (mL) | Relative Orbital Volume Difference (%) | The Distance from Infraorbital Margin to the Posterior Part of the Fracture |
|---|---|---|---|---|---|---|
| 1 | No | | No | 0.4 | 9.8 | 15.5 |
| 2 | No | | 1 | 0.2 | 9.9 | 18.3 |
| 3 | No | | No | 1 | 12.5 | 21.8 |
| 4 | No | | No | 0.2 | 0 | 23.9 |
| 5 | No | | No | 1.2 | 0.4 | 24.1 |
| 6 | Yes | Pretrauma | 2 | 0.3 | 8.5 | 20.2 |
| 7 | No | | No | 1.1 | 6 | 21.5 |
| 8 | No | | 1 | 0.2 | 3.5 | 29.1 |
| 9 | Yes | Posttrauma | 2 | 1 | 0.5 | 24.3 |
| 10 | No | | No | 0.2 | 0.05 | 22.4 |
| 11 | Yes | Pretrauma | No | 1.7 | 0.5 | 23.3 |
| 12 | No | | No | 2 | 11.8 | 27.3 |
| 13 | Yes | Posttrauma | 1 | 1.7 | 11.4 | 29.3 |
| 14 | No | | 2 | 1.7 | 2.7 | 27.6 |
| 15 | No | | 2 | 2.2 | 10.7 | 31.8 |
| 16 | No | | No | 0.5 | 18.7 | 20.6 |
| 17 | No | | No | 1.1 | 1.6 | 24.1 |
| 18 | No | | No | 0.6 | 7.8 | 20.8 |
| 19 | Yes | Posttrauma | 4 | 1.5 | 9.6 | 35 |
| 20 | Yes | Pretrauma | No | 1 | 17.2 | 32 |
| 21 | Yes | Pretrauma | No | 1.6 | 14.9 | 26 |
| 22 | No | | 1 | 1 | 4.2 | 16.9 |
| 23 | Yes | Posttrauma | No | 1 | 1.5 | 20.7 |

# RESULTS

## PAPER I

Eighty-nine patients were contacted and 43 (48%) responded. Twenty of those were excluded: two appeared to have had a medial orbital wall fracture instead of an orbital floor fracture, and 12 had been scanned with CT slices thicker than 2 mm. Finally, six individuals did not show up for the examination. Thus, 23 individuals were included in the study. There were 19 men and 4 women. They had a mean age of 41 (17 to 74). The mean time from injury to examination was 22 months (6 to 46). The CT scans of the patients were performed within 1.9 days (1, 2, 5–8, 10) after the injury.
The mean herniated volume was 1.0 ml (0.2 to 2.2). The relative volume difference between the fractured and the non-fractured orbit was 1.4 ml (0 to 3.4) or in percentage terms 8.6% (0 to 18.7%;) (Table 3).

The corresponding relative mean volume difference in the control group was 0.6 ml (0.1 to 1.4) and 2.5%. The correlation between herniated orbital volume and the relative orbital volume difference between orbits was found to be poor (figure 24). The relative difference in orbital volumes were significantly different between the two groups (p<0.049; Mann-Whitney U test).

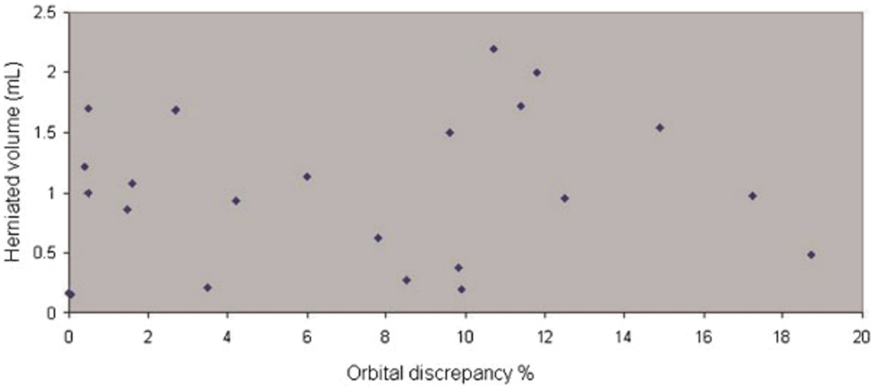



*Figure 24. Orbital discrepancy % (x) by herniated volume ml (y).*

The analysis of the reproducibility of the orbital volume measurements by the two investigators revealed a mean value of the differences between the operators as 0.26 (standard deviation 1.39). The ICC, evaluated by a two-way mixed-effects model, was 0.82 (95% confidence interval from 0.700 to 0.898 (figure 25).

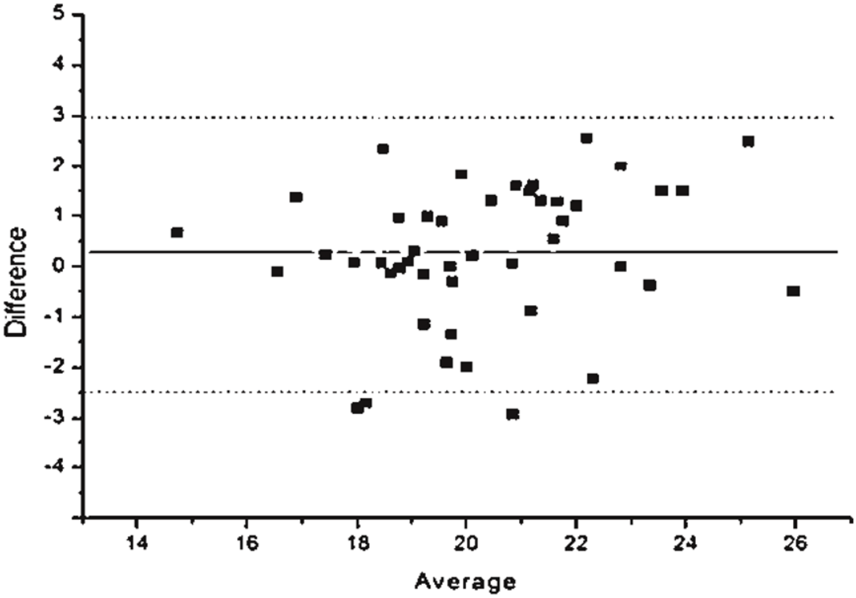



*Figure 25. The analysis of the reproducibility of the orbital volume measurements. Mean value of the differences between the operators was 0.26 (standard deviation 1.39).*

Five of the 23 patients presented with an enophthalmus mean of 2 mm. The mean herniated volume in these cases was 1.3 ml (0.3 to 2.2). There was no correlation between the herniated volume and the degree of enophthalmus ($r^2$ value; figure 26).

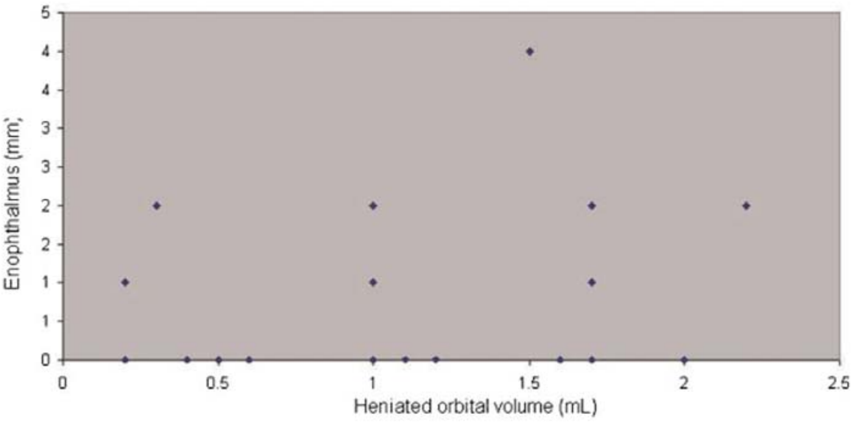



*Figure 26. Herniated orbital volume (x) by enophthalmus (y).*

We did not find that large relative changes in orbital volume in orbital fractures correlated with posttraumatic enophthalmus (figure 27).

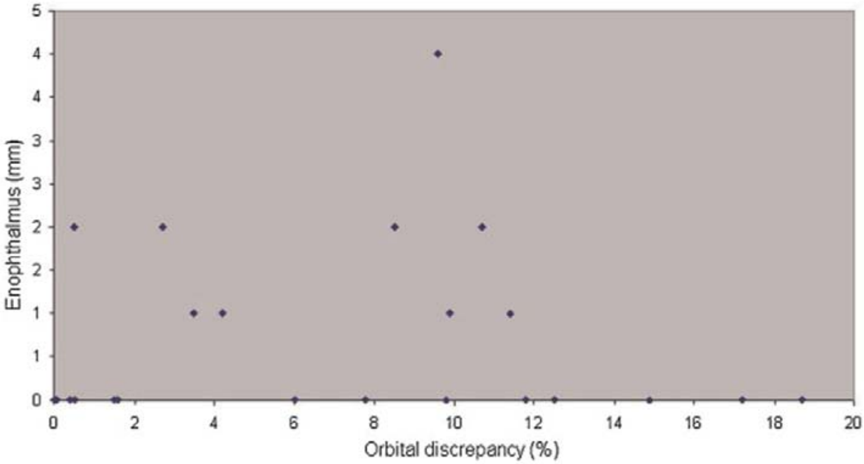



*Figure 27. Orbital discrepancy (x) by enophthalmus (y).*

Eight patients experienced an intermittent diplopia, and four of those could be related to their orbital floor fracture. (see table 5). The mean distance from the infraorbital rim to the anterior part of the fracture was 7.8 mm (2.0 to 17.1) and to the posterior part of the fracture, 23.0 mm (16.9 to 35.0). A correlation analysis of the orbital volume (y) of the fractured orbit and the localization of the fracture (x) was performed that showed a weak ($r^2$¼0.25) but significantly ($p<0.001$) increased risk of larger herniation in fractures that extend more posteriorly.

One plausible explanation for this might be that the distance from orbital rim to the posterior location of the fractures is longer in larger orbits ($r^2$¼0.30; p<0.01). The longer and larger an orbit is, the more likely to lead to a larger herniation. Two measurements (in millimeters) of the fracture localization were evaluated from the CT scan (i.e., the distance from the margin to the anterior and the posterior part of the fracture; Table 5). The analysis revealed a positive correlation between the orbital volume and the posterior localization of the fracture (r2¼0.50; p<0.05). Two of five patients with enophthalmus had posteriorly extended fractures 31.8 and 35.0 mm (figure 28).

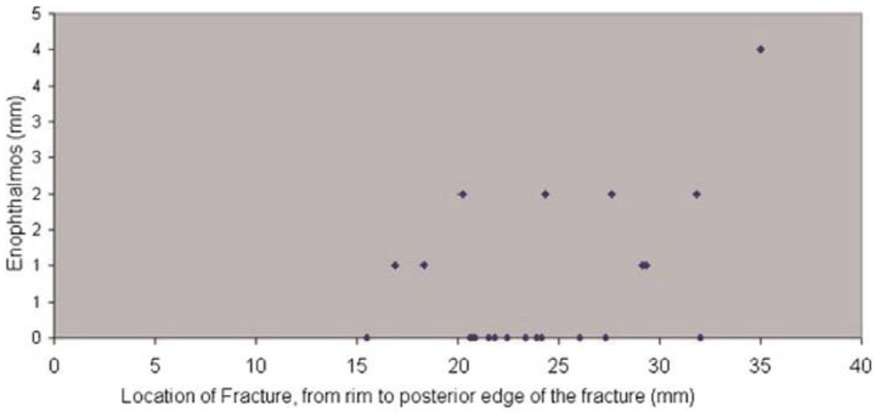



*Figure 28. Location of fracture from rim to the posterior edge of the fracture (x) by enophthalmus (y).*

Only one patient (No. 19) in the study group was cosmetically discomforted by the enophthalmus, which measured 4 mm.

*Table 4. Summary of clinical findings and the surgeons' opinion. X: no agreement on the management. Surg: agreement on surgery needed. No surg: agreement on no surgery needed. Y: no agreement on the risk for late enophthalmus. Sub. risk: agreement on substantial risk for late enophthalmus. No risk: agreement on small or no risk for late enophthalmus.*

| Case | Diplopia at the first visit | Operated | Inter mittent diplopia at the follow up | Late enophthalmus (mm) | Operated | ENT | Facial p. | Ocular p. | Oral Maxillof. | Plastic | Ger- SW | SWE | USA | All surgeons |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | No | No | No | 2 | No | X, Y | X, Y | X, no risk | X, Y | Surg, Y | Surg, sub risk | X, Y | X, Y | X, Y |
| 2 | No | No | No | 1 | No | X, no risk | X, Y | X, Y | X, Y | Surg, Y | Surg, sub risk | X, no risk | X, Y | X, Y |
| 3 | No | Yes | No | 0 | Yes | Surg, Y | Surg, Y | X, Y | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, Y | Surg, sub risk | Surg, Y |
| 4 | No | No | No | 0 | No | No surg, no risk | No surg, no risk | X, no risk | No surg, no risk | No surg, no risk | X, Y | No surg, no risk | No surg, no risk | No surg, no risk |
| 5 | No | No | No | 0 | No | X, Y | X, Y | X, Y | X, Y | X, Y | Surg, Y | X, Y | X, Y | X, Y |
| 6 | Yes | Yes | No | 0 | Yes | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk | Surg, No risk |
| 7 | No | Yes | No | 1 | Yes | Surg, sub risk | Surg, sub risk | X, Y | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk |
| 8 | No | No | No | 1 | No | X, Y | X, Y | x, no risk | surg, Y | No surg, no risk | Surg, sub risk | X, Y | X, no risk | X, Y |
| 9 | Yes | No | No | 2 | No | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk |
| 10 | No | No | Yes | 4 | No | X, Y | X, Y | X, Y | X, Y | Surg, sub risk | Surg, sub risk | X, Y | X, Y | X, Y |
| 11 | No | No | Yes | 2 | No | No surg, no risk | X, Y | No surg, no risk | X, no risk | Surg, X | X, no risk | No surg, no risk | X, Y | X, sub risk |

## PAPER II

The mean time from injury to the examination was 33 months (6–54). Three patients (cases 1, 9 and 11) developed 2 mm late enophthalmus and one patient (case 10) 4 mm late enophthalmus. At the follow up, 2 patients (cases 10 and 11) experienced intermittent diplopia, but no patient suffered from persisting diplopia. For details please see Table 4.

The experience level of the participating surgeons in BOF reconstruction was as follows: 3 surgeons (7%) had experience of 10 cases, 4 surgeons (9%) of 20 cases, 6 surgeons (13%) of 30 cases, 1 surgeon (2%) of 40 cases and 32 surgeons (70%) >40 cases of BOF reconstructions, figure 29.

As to the question whether surgery was needed or not, all the surgeons were in agreement (75% agreed) in 5 of the 11 cases, and the overall agreement between all pairs of surgeons was 64%, k = 0.29. In the subgroup analyses for different specialities, the ocular plastic surgeons were in agreement in 3 cases (overall agreement 49%, k = 0.02), facial plastic surgeons in 5 cases (overall agreement 63%, k = 0.26), ENT surgeons (overall agreement 68%, k = 0.37) and oral maxillofacial surgeons in 6 cases (overall agreement 65%, k = 0.31), and the plastic surgeons in 10 cases (overall agreement 84%, k = 0.67). When looking at country of origin, we found that surgeons from USA and Sweden were in agreement in 5 (overall agreement 62%, k = 0.24), and 6 cases (overall agreement 68%, k = 0.35) respectively, while surgeons from Switzerland–Germany agreed on 9 cases (overall agreement 84%, k = 0.67), figure 30.

In the question regarding the risk for late enophthalmus, all the surgeons as a group were in agreement in 5 cases (overall agreement 62%, k = 0.23). Regarding the subgroups the facial plastic surgeons were in agreement in 4 cases (overall agreement 57%, k = 0.13), ocular plastic surgeons in 6 cases (overall agreement 62%, k = 0.24), ENT surgeons in 6 cases (overall agreement 67%, k = 0.32), and oral maxillofacial surgeons in 6 cases (overall agreement 60%, k = 0.20). Regarding country of origin, surgeons from the USA agreed in 6 cases (overall agreement 61%, k = 0.22), those from Sweden in 6 cases (overall agreement 66%, k = 0.32), whilst surgeons from Switzerland–Germany agreed in 9 cases (overall agreement 72%, k = 0.43). All the groups were in agreement on the management, timing of surgery and the risk for enophthalmus in cases 6 and 9. Except ocular plastics, all groups were also in agreement on the management of case 3. In reality, cases 3, 6 and 7 underwent surgical intervention and at the follow up they had no diplopia and no enopht-

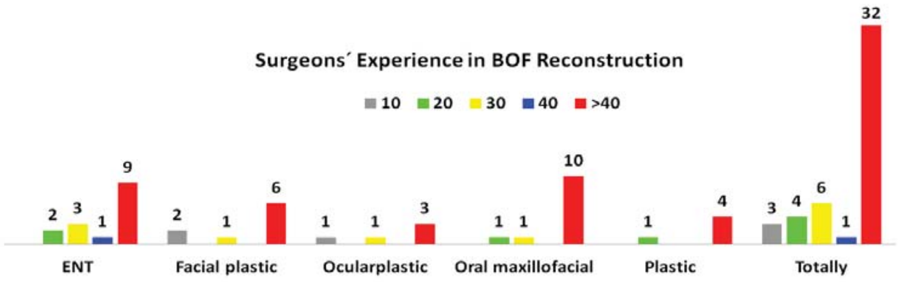



*Figure 29. Surgeons'experience in BOF*

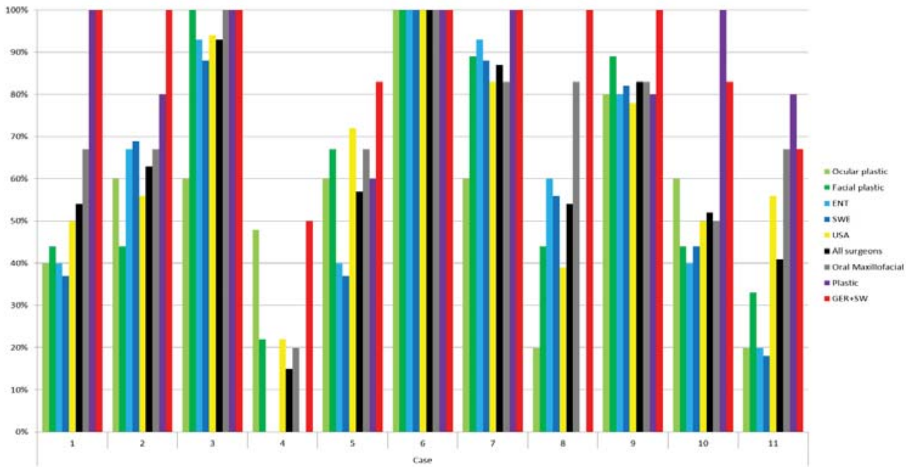



*Figure 30. Surgery needed.*

halmus. Case 9 refused surgical intervention and had 2 mm enophthalmus but no diplopia at the follow up. This patient was not interested in correction of her enophthalmus. For details please see Table 4.

In case 8 the oral maxillofacial surgeons and surgeons from Switzerland–Germany were in agreement that surgery was needed, plastic surgeons agreed that surgery was not needed, whilst there were no agreement between the other groups. In this case no surgery was performed and the patient showed no enophthalmus and no diplopia at the follow up. In case 5 the surgeons from Switzerland–Germany were in agreement for the need for surgery, whereas there was no agreement amongst the other groups. This case was treated non-surgically and showed neither enophthalmus nor diplopia at the follow up. Except for the surgeons from Switzerland–Germany and plastic surgeons, no other group was in agreement regarding the need of surgery in cases 1, 2 and 10. Interestingly, case 10 is the only patient in this study who showed intermittent diplopia and 4 mm late enophthalmus at the 6 month follow up, a displacement of the bulb which is considered cosmetically disturbing and should have been operated at an early stage. In this case only the plastic surgeons and surgeons from Switzerland–Germany were in agreement that surgery was needed. The surgeons from Switzerland–Germany advocated surgery in the 9 of the 11 cases, plastic surgeons in 8 cases, the oral maxillofacial surgeons in 5 cases, all the surgeons as a group, the ENT surgeons, facial plastic surgeons, surgeons from USA and Sweden in 4 cases and ocular plastics in 2 cases. When examining the opinions of the surgeons from Switzerland–Germany this group was in agreement that surgery was needed in 9 of 11 cases, but they did not agree that surgery was not needed in any of the 11 cases. We also found that when the groups were in agreement that there was no or limited risk for late enophthalmus, they also agreed that surgery was not needed. The correlation between the need for surgery and the substantial risk for late enophthalmus was, however, only 73%.

## PAPER III, IV AND V

### CLINICAL CHARACTERISTICS

In total 151 patients were included and 126 patients (55 female, 71 male) completed paper III, IV and V. Twenty five patients dropped out, 3 patients from the observational and 22 from the non-operated group. There was no drop out between the patients who underwent surgical treatment in any groups.
There was a significant difference only between the patients in the entrapment and the impingement group in age ($p < 0.05$) and cause of injury ($p < 0.05$) in baseline characteristics. For more details about clinical characteristics of the patients see table 5.

The median age was significantly lower in the entrapment group compared to remaining groups ($p < 0.05$). While in entrapment group sport injury was the most common cause, in the remaining groups the most common cause of injury was falling followed by assault.
There was no significant difference in the time from injury to inclusion (0-21 days) between the groups. However, there was significant difference in the time from inclusion to surgery between the entrapment group and remaining groups ($p < 0.05$).

After inclusion, patients were followed up with up to 5 visits for at least one year after the injury or surgery: 1st visit (1-3 weeks post injury), 2nd visit (3-7 weeks post injury), 3rd visit (8-16 weeks post injury), visit 4th (2-36 weeks post injury) and visit 5th (49-208 weeks post injury or surgery).

| Baseline characteristics | Paper III | | Paper IV | | Paper V | |
|---|---|---|---|---|---|---|
| | Entrapment | Impingement | Non-operated | Operated | Observational | Surgical |
| **No of patients completed the study** | 10 | 11 | 71 | 8 | 10 | 16 |
| **Age, years** | 14 (11-23) | 29 (17-77) | 50 (19-78) | 30 (12-73) | 54 (30-78) | 51 (23-73) |
| **Gender (F/M)** | 5/5 | 4/7 | 32/39 | 4/4 | 3/7 | 7/9 |
| **Injured Eye (L/R)** | 6/4 | 5/6 | 44/27 | 4/4 | 4/6 | 5/11 |
| **Cause of injury** | | | | | | |
| **Falling** | 0 | 4 | 36 | 3 | 6 | 8 |
| **Assault** | 0 | 4 | 19 | 3 | 3 | 6 |
| **Sports injury** | 8 | 2 | 8 | 1 | 0 | 1 |
| **Traffic accident** | 1 | 0 | 2 | 0 | 0 | 0 |
| **Other** | 1 | 1 | 6 | 1 | 1 | 1 |
| **Injury to inclusion, days** | 1.5 (0-16) | 5 (1-12) | 3 (0-16) | 3 (0-21) | 6 (0-12) | 4 (1-12) |
| **Satisfaction with treatment at final control, %** | 100 | 100 | 98 | 100 | 100 | 100 |

*Table 5. Baseline characteristics. The patients were divided into the groups: Entrapment and Impingement, Non- operated and Operated, Observational and Surgical.*

Minimum 98% of the patients in both groups were satisfied with the treatment that they received at the final control.

## TIME ASPECTS

### Paper III

The median time from injury to inclusion was 1.5 (0-16) days in the entrapment group and 5 (1-12) days in the impingement group. The median time from injury to surgery was 1.5 (0-17) days or 36 (8-413) hours for the entrapment group and 7 (2-14) days or 168 (48-326) hours for the impingement group. There was a significant difference (p=0.006) in median time from inclusion to surgery which was 0 (0-1) days for the entrapment group and 1.0 (0.2-4.8) days for the impingement group, (see figure 31).

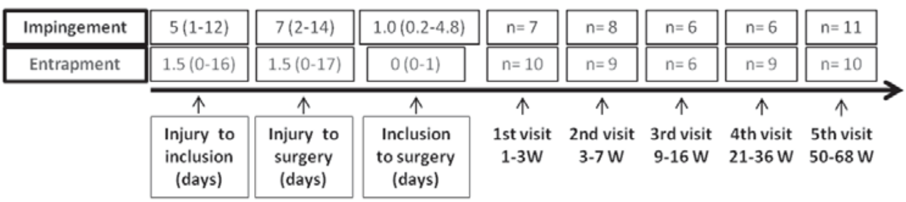



*Figure 31. Flowchart of patients with entrapment or impingement. W=weeks.*

In the entrapment group 5 patients were operated on within 24h and 5 patients between 48-432 hours. Despite guidelines that a patient with entrapped rectus muscle need surgical intervention within 24 hours, the median time from injury to surgery was 1.5 (0-17) days in this group. Four patients underwent surgery 4-18 days post injury with the following reasons: One patient was injured in a ski accident in another country where a CT scan and MRI was performed and the patient was informed that there was no entrapment of ocular muscle. 4 days passed before the patient was admitted to our department and operated on the same day. In two of the cases there were doctors' delays due to inadequate ocular motility examination in addition to radiologic misinterpretation of the CT scan. In one case, patient delay was the reason for the late surgical intervention.

Two patients, both in impingement group had the longest waiting time from inclusion to surgery. One patient waited 7 days to stabilize a cardiac issue. In another patient there was a surgeon's delay of 4 days due to summer vacation.

We could not find any correlation between the time from injury to surgery and the ocular motility, diplopia and hypesthesia in any of the groups at final control.

## Paper IV

10 % (n=8) of the patients who were not assessed to benefit from surgical intervention, development visible deformity (observed at 2nd or 3rd visit) and choose to be treated surgically. The median age between this group was 30 years (12-73) and in the non-operated group 50 years (19-78) (see figure 32).

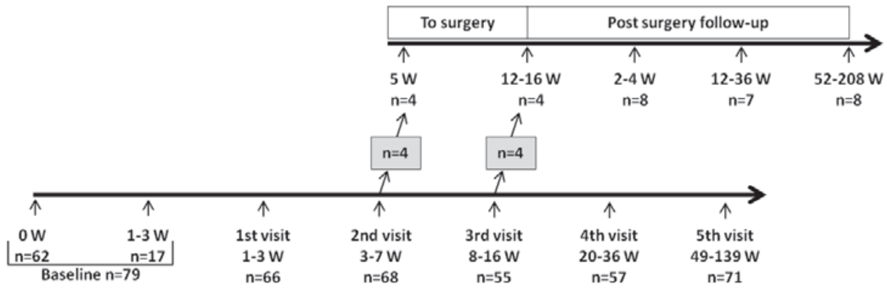



*Figure 32. Flowchart of patients in paper 4. 10% of the patients (n=8) choose to be treated surgically due to the development of visible deformity. W=weeks.*

### Paper V

In the observational group, 6 patients developed a visible deformity with a median of 34 (16-150) days after the injury and 5 of these patients chose to proceed to surgery which was performed 37 (17-170) days after the injury. In the surgical group, the median time from injury to surgery was 13 (3-17) days (figure 33).

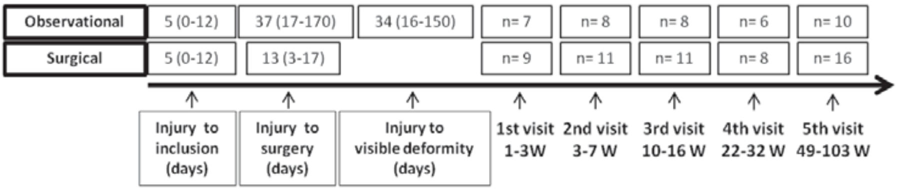



*Figure 33. Flowchart of patients randomized to Observational vs Surgical treatment W=weeks.*

## OCULAR MOTILITY LIMITATION

All the patients in the paper III had ocular motility limitation in at least one gaze direction at inclusion. Postoperatively, ocular motility improved compared to that at inclusion. Motility limitation was observed until the 2nd postoperative visit (3-7 weeks) post injury. It resolved gradually and was not observed in any of the patients at the 3rd, 4th or 5th (1 year) visits.

None of the patients in paper IV and V had ocular motility limitation at inclusion or at final control.

*Paper III*

All the patients with inferior orbital wall fractures had inferior rectus muscle involved. According to the physicians' findings, all the patients had limitation to elevate the injured eye. Three patients also had limitation to depress the injured eye. After surgery, ocular motility was normalized in 50% (n=5) but partially remained in 40% (n=4) of the patients and in 10% (n=1) of the patient there was no improvement of the ocular motility at the 1st postoperative visit (1-3 weeks). This partial limitation was still found in 2 patients at the 2nd postoperative visit (3-7 weeks) post injury. At the remaining follow-up appointments, none of the patients showed any ocular motility limitations in any gaze direction.

One patient with entrapment of the inferior rectus muscle was operated on within 24 hours. Two weeks after the initial surgery there was no improvement of the ocular motility. The patient was taken to the OR the same day. Forced duction test was similar to the ipsilateral unfractured side. When the orbital floor was explored again, entrapped connective tissue was found in the posterior end of the trapdoor fracture and released. One week after the re-exploration, the ocular motility had improved and was normalized at the 3rd visit (9-16 weeks).

When patients were asked at inclusion they all reported a sense of movement impairment of the affected eye. This decreased gradually and at the final visit only one patient reported affected eye movements but did not report any diplopia. However, eye movement restriction was not seen in the physicians' examination findings. Patients experienced ocular motility disorder in slightly higher frequency than the physicians` findings (figure 34).

Five patients had inferomedial BOF, 2 of them had medial rectus muscle impingement and 3 of them had inferior rectus muscle impingement. 4 patients had inferior BOF with inferior rectus muscle impingement and 2 patients with medial BOF had medial rectus muscle impingement. All the patients with medial rectus impingement (n=4) had paresis of adduction of the injured eye (3 right and 1 left). 7 patients had limitation to elevate the injured eye and 3 had limitation to depress the eye. Postoperatively, ocular motility limitation was only found in 2 patients up to the 2nd visit (3-7 weeks) after the injury. At the remaining follow-up appointments, none of the patients showed any ocular motility limitations in any gaze.

When patients were asked at inclusion 10/11 reported a sense of movement impairment of the affected eye. This decreased gradually and at the final control only two patients reported a sense of affected eye movement but neither of these two patients reported diplopia. However, eye movement restriction was not seen in the physicians' examination findings. Patients experienced ocular motility disorder in slightly higher frequency than the physicians` findings (figure 35).

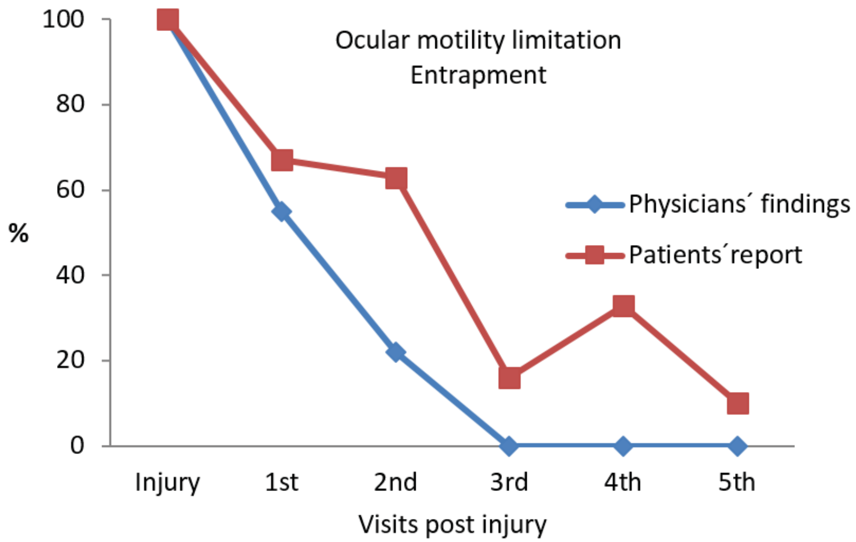



*Figure 34. Improvement in ocular motility in the entrapment group.*

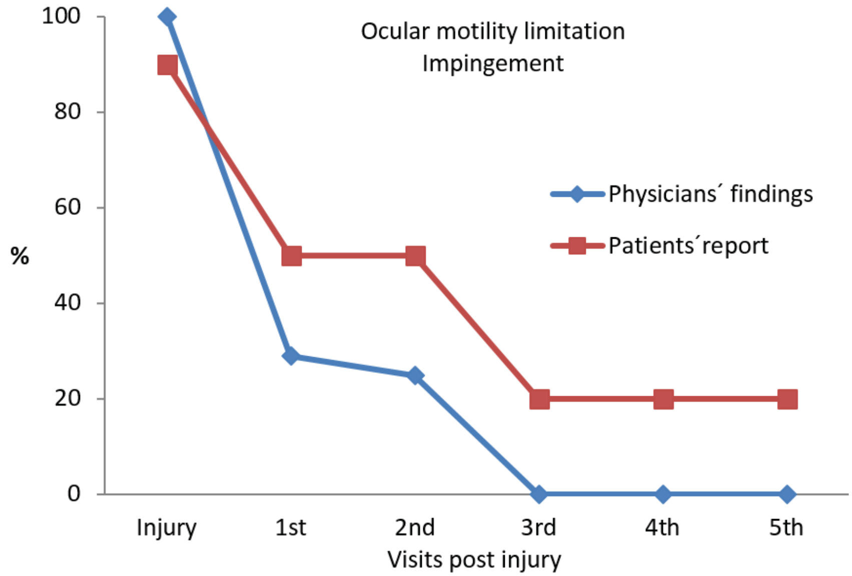



*Figure 35. Improvement in ocular motility limitation in the impingement group.*

## SURGICAL INTERVENTION

*Paper III*

**Entrapment group**

Forced duction test was performed under general anesthesia prior to surgery in all patients and was found positive in 9 patients and negative in 1 patient. Through a transconjuctival approach, the orbital floor was exposed and the incarcerated orbital tissue was released from the trapdoor like fracture. The dissection was continued along the fracture by a few millimeters to 1 cm behind the posterior end of the fracture to make sure that there was no more incarcerated orbital tissue. No orbital implant was inserted. The surgery was completed by performing a new forced duction test. In all the cases the forced duction test was negative.

The patient with a negative intra operative forced duction test was an 18 yo with radiological evidence of entrapment who was operated 17 days post injury. On discharge this patient had recovered totally from diplopia and ocular motility limitation.

**Impingement group**

Forced duction test was performed under general anesthesia prior to surgery in 9 patients and was found positive in 7 patients, negative in 2 patients (1 inferior and 1 medial rectus) and not performed in 2 patients (1 inferior and 1 medial rectus). 7 of the fractures required reconstruction by an orbital implant (SynPOR, titanium mesh titanium mash covered by polyethylene). The remaining 4 patients did not receive an implant due to the small size of the fracture.

*Paper IV*

10 % (n=8) of the patients who were not assessed to benefit from surgical intervention, developed visible deformity (observed at 2nd visit 3-7 W or 3rd visit 8-16 W post injury) and choose to be treated surgically, figure 33. Reconstructions of the BOF were performed with 1-2 weeks after that the deformities were observed. The median age in this group was 30 years (12-73) and in the non-operated group 50 years (19-78).

*Paper V*

In the observational group, 6 patients developed a visible deformity with a median of 34 (16-150) days after the injury and 5 of these patients chose to proceed to surgery which was performed 37 (17-170) days after the injury. In the surgical group, the median time from injury to surgery was 13 (3-17) days.

## DIPLOPIA

*Paper III*

**Entrapment group**

According to both the physicians´ findings and patients´ reports, all the patients had diplopia at inclusion. Diplopia was found in 7 patients at the 1st visit (1-3 weeks) post injury and in 6 patients at the 2nd visit (3-7 weeks) post injury. At the final visit, diplopia was resolved in all patients except in two, who reported diplopia in extreme upward gaze on examination. However, these two patients were back to normal life and had not been aware of their diplopia in extreme upward gaze. They were both 14 years old at the time of injury and were operated 4 and 5 days after the injury, due to doctor´s delay. No ocular motility limitation or enophthalmus was observed or reported by these 2 patients (figure 36).

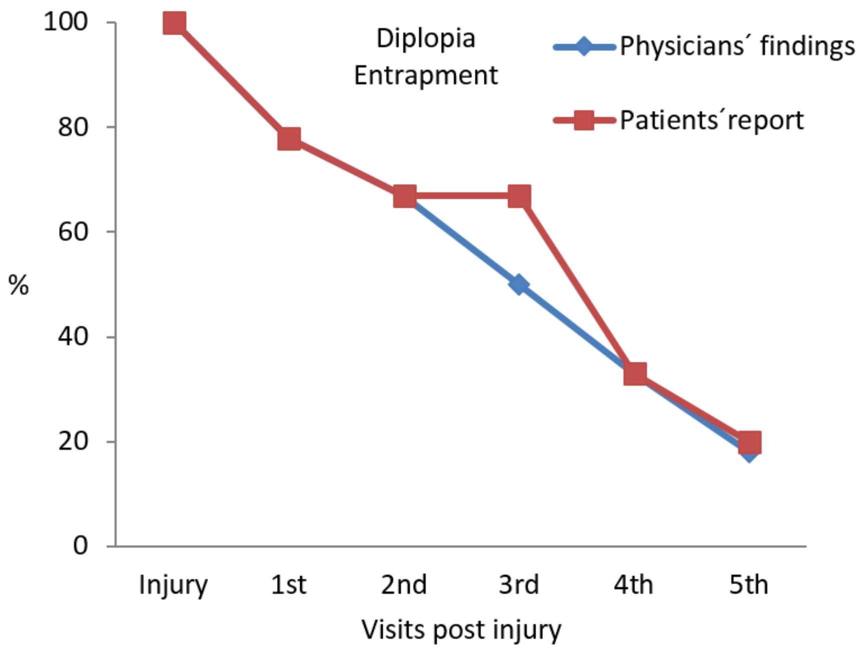



*Figure 36. Improvement of diplopia in the entrapment group.*

**Impingement group**

According to both the physicians´ findings and patients´ reports, all the patients had diplopia at inclusion. Diplopia was reported by 7 patients at the 1st visit (1-3 weeks), by 4 patients at the 2nd visit (4-7weeks), by 3 patients at the 3rd visit (12-16 weeks) and by 2 patients at the 4th visit (21-32 weeks) post injury. Diplopia was not reported at the final 5th visit in this group (figure 37).

*Paper IV*

**Non-operated group**

There was a significant improvement, according to the physicians' findings (p=0.0001) as well as the patients' self-reports (p=0.0002), in the number of patients experiencing diplopia at inclusion compared to final control. According to the physicians' findings, 33% of the patients (n=23) experienced diplopia at inclusion but only 3 % (n=2) had diplopia at final control. One patient had diplopia in up gaze (inferomedial fracture with 0.5 ml herniation) and the other patient in down gaze (inferior fracture with 0.9 ml herniation and 1.2 cm2 fracture area) and none of them had a visible deformity. According to the patients self-report, 34% (n=24) experienced diplopia at inclusion and this remained in 7% (n=5) at final control. Patients experienced diplopia in slightly higher frequency than the physicians` findings, (see figure 38).

**Operated group**

There was no statistically significant improvement, according to the physicians' findings (p=0.07) as well as the patients' self-reports (p=0.21), in the number of patients experiencing diplopia at inclusion compared to the final control. In the physicians' findings, 50% of the patients (n=4) experienced diplopia at inclusion and none experienced diplopia at final control. In the patients' self-report, 38% of the patients (n=3) experienced diplopia at inclusion while 13% of the patients (n=1) experienced diplopia at the final control.

*Paper V*

**Observational group**

According to both patients´ and physicians´ report, 50% (n=5) of the patients had diplopia at inclusion and this remained with down gaze in 20% (n=2) of the patients at the final control. Due to hypoglobus and enophthalmus, these two patients proceeded to surgery 17 and 37 days after injury, respectively. No patient needed surgery due to diplopia.

**Surgical group**

Patients reported diplopia in 56% (n=9) of the cases and physicians in 50% (n=8) of the cases at inclusion. Diplopia remained in 6% (n=1) of the patients, which was observed in lateral gaze at the final control.

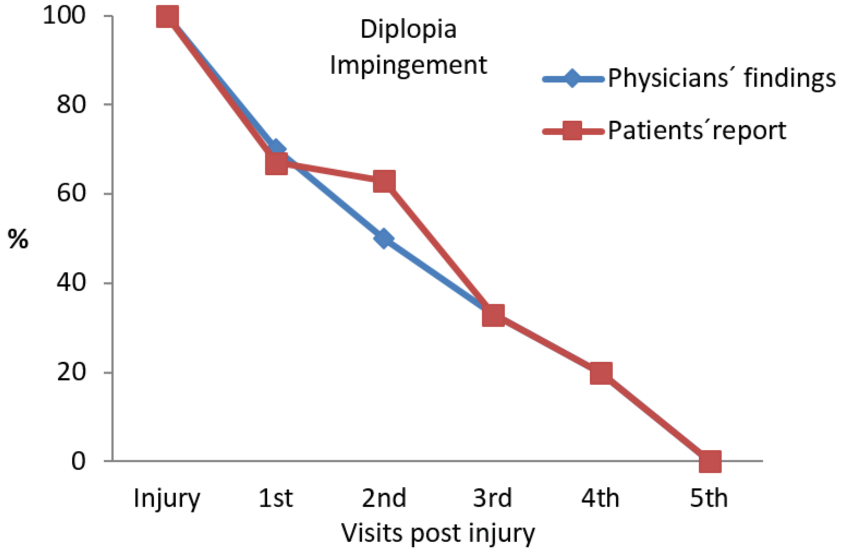



*Figure 37. Improvement of diplopia in the impingement group.*

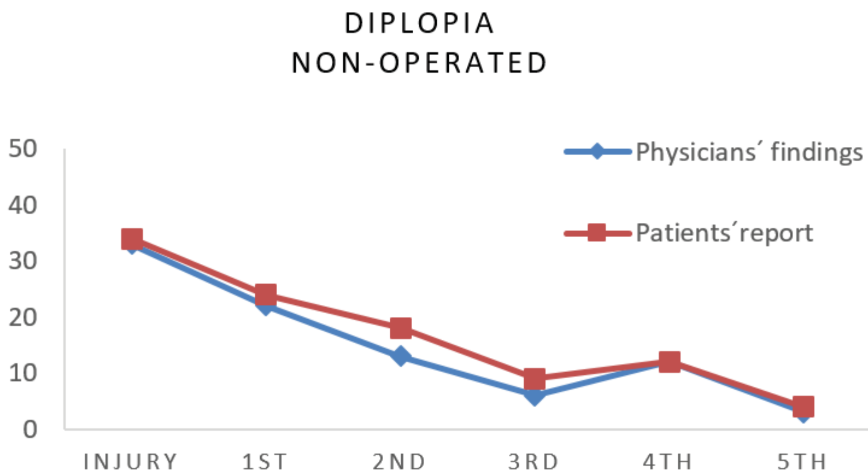



*Figure 38. Improvement of diplopia in the non-operated group.*

## HYPESTHESIA

*Paper III*

**Entrapment group**

Hypesthesia was reported and observed in one patient at inclusion. Postoperatively, 2 patients had hypesthesia at the 1st visit (1-3 weeks) and 1 patient had hypesthesia at the 2nd visit (3-7 weeks) post injury. At the following visits none of the patients reported hypesthesia.

**Impingement group**

At the inclusion, hypesthesia was observed and reported in 4 patients. One patient recovered from hypesthesia while one patient developed hypesthesia postoperatively. At the final visit 4 patients still had hypesthesia. This finding was congruent with the patients' report.

*Paper IV*

**Non-operated group**

We found that, there was a significant improvement in hypesthesia from baseline according to both the physicians' findings (p=0.001) as well as the patients' self-reports (p=0.002). In the physicians' findings, 51% of the patients (n=36) had hypesthesia at inclusion and 18% (n=13) still had hypesthesia at final control. 49% of the patients (n=35) noted hypesthesia themselves at inclusion and 23% (n=16) had hypesthesia at final control.

**Operated group**

50% of patients (n=4) experienced hypesthesia according to the physicians´ findings at inclusion and at final control there was no improvement. According to the patients' self-reports, 63% (n=5) experienced hypesthesia at inclusion while 50% (n=4) experienced hypesthesia at the final control (week 52–208). There was no statistical significant improvement within the group at the final control compared to baseline.

*Paper V*

**Observational group**

According to both patients´ and physicians´ report, 60% (n=6) of the patients had hypesthesia of the inferior orbital nerve at inclusion and it remained in 40% (n=4) of the patients at final control. One patient developed hypesthesia after undergoing surgery.

**Surgical group**
According to both patients´ and physicians´ report, 50% (n=8) of the patients had hypesthesia of the inferior orbital nerve at inclusion. At final control, 4 of them still had hypesthesia and another 4 developed hypesthesia after undergoing surgery.

## CT SCAN EVALUATIONS

*Paper III*
**Entrapment group**
Ten patients with median age of 14 (11-23) years had ocular motility restriction and radiological signs of orbital wall fracture on the preoperative CT scan (figure 9).

**Impingement group**
Eleven patients with median age of 29 (17-77) years had ocular motility restriction and radiological signs of orbital BOF on the preoperative CT scan. In this group 4 patients had inferior wall fracture (figure 10), 2 patients had medial wall fracture (figure 39) and 5 patients had inferomedial wall fracture (figure 40).

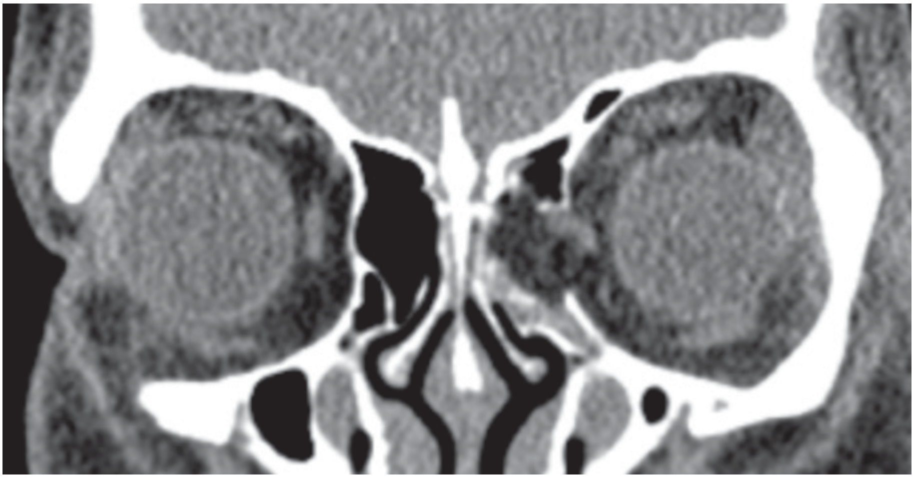


*Figure 39. CT scan of a patient with BOF in left orbit with limitation to adduct the left eye was observed 7 days after the injury. This patient was considered to have impingement of left medial rectus muscle.*

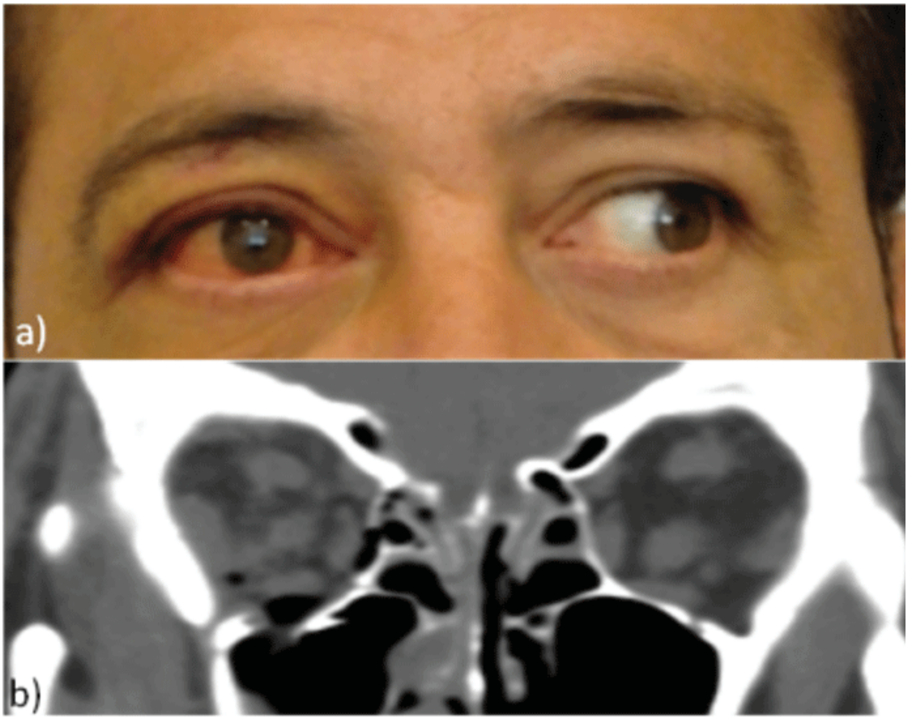



*Figure 40. CT scan (a) of a patient with inferomedial BOF of right orbit and paresis of right medial rectus muscle and limitation to adduct the right eye remaining 7 days after the injury (b). This patient was considered to have impingement of right medial rectus muscle.*

*Paper IV*

**Non-operated and operated groups**

Depending on which orbital walls were fractured, patients were categorized as one of three fracture types: inferior wall, inferomedial wall and medial wall. 68% (n=54) of the patients had inferior wall fracture, 23% (n=18) inferomedial wall fracture and 9% (n=7) had a medial wall fracture. The results from CT-scan measurements were analyzed and compared between the patients with visible and no visible deformity within each fracture type, see table 1.

*Inferior wall fracture*

There were significant differences when comparing patients with visible and no visible deformity in: distance from inferior orbital rim to the posterior edge of the fracture (p=0.009), width of the fracture (p=0.04), ratio between the largest width of the fracture and the total width of the fractured orbital wall (p=0.01), total area of the fracture (p=0.048), the ratio between fracture and the fractured orbital wall areas (p=0.038) and the volume of the herniated orbital tissue (p=0.001). We used a ROC curve to determine the cut-off level for visible deformity in patients with inferior wall fracture. ROC curve results are presented in table 1. The highest ROC curve was for volume of herniated orbital tissue and the AUC was 0.77 (see figure 41), giving a cut-off level at 1.0 ml. We sub-divided the patients into 2 groups, those with < 1.0 ml herniation and those with ≥ 1.0 ml herniation. The CT scan measurements were analyzed and compared within each group, see table 1.

*Inferior wall fracture with <1.0 ml herniation*

There were significant differences when comparing patients with visible (n=4) and no visible deformity (n=24) in: total area of the fracture (p=0.048) and the ratio between fracture and the fractured orbital wall areas (p=0.035). A ROC curve for all the measurements predicting the visible deformity (n=4) was performed, see table 1. We found that AUC was 0.83 for the ratio between fracture and the fractured orbital wall areas giving a cut-off level at 42%. We also found that the AUC was 0.81 for the total area of the fracture giving a cut-off level at 2.3 $cm^2$, (see figure 42), see table 1.

In patients with inferior wall fracture and a herniation < 1.0 ml, a visible deformity was found when the ratio between the fracture and the fractured orbital wall areas was ≥ 42%, or the total area of the fracture was ≥ 2.3 $cm^2$.

*Inferior wall fracture with ≥ 1.0 ml herniation*

There was a significant difference when comparing patients with visible (n=12) and no visible (n=14) deformity in the distance from inferior orbital rim to the posterior edge of the fracture (p=0.025). A ROC curve for the distance predicting the visible deformity (n=12) was performed. We found that the AUC was 0.75 and the fracture distance from inferior orbital rim to the posterior edge of the fracture had a cut-off level at 3.0 cm (figure 43), see table 1.

In patients with inferior wall fracture and a herniation ≥ 1.0 ml, a visible deformity was found when the fracture distance from inferior orbital rim to the posterior edge of the fracture was ≥ 3.0 cm.

*Inferomedial wall fracture*

There were significant differences when comparing patients with visible (n=11) and no visible (n=7) deformity in: the total area of the fracture (p=0.020) and the volume of the herniated orbital tissue (p=0.0007). ROC curves for both these two measurements predicting the visible deformity (n=11) were performed. We found that the AUC was 0.98 for the volume of the herniated orbital tissue, giving a cut-off level at 0.9 ml (figure 44), and 0.84 for area of the fracture, giving a cut-off level at 4.8 $cm^2$, see table 1.

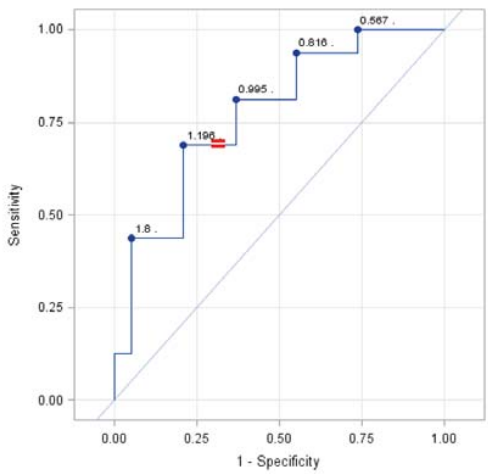



*Figure 41.*
*AUC for herniated orbital volume (ml) in inferior wall fractures.*

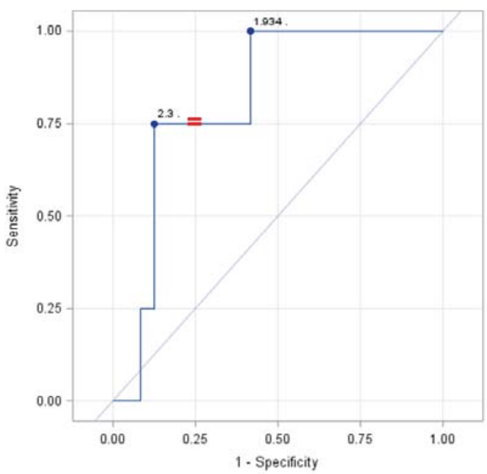



*Figure 42.*
*AUC for fractured area ($cm^2$) in inferior wall fractures with < 1.0 ml herniation.*

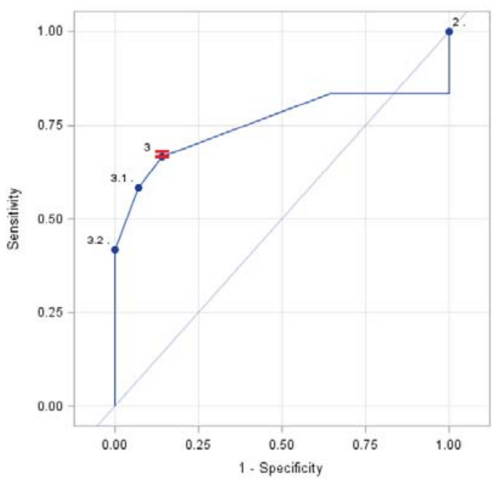



*Figure 43.*
*AUC for distance from inferior orbital rim to the posterior edge of the fracture in inferior wall fractures with ≥ 1.0 ml herniation.*

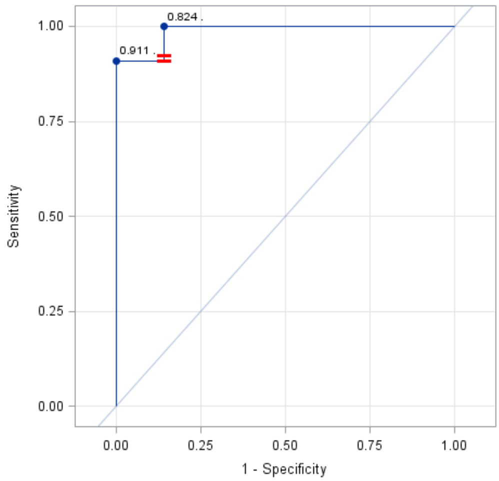



*Figure 44.*
*AUC for herniated orbital volume (ml) in inferomedial wall fractures.*

In patients with inferomedial fracture a visible deformity was found when the herniation was ≥ 0.9 ml.

*Medial wall fracture*
There were no significant differences in CT scan measurements when comparing patients with visible (n=2) and no visible (n=5) deformity, see table 1.

*Paper V*
**Observational group**
We found a statistically significant difference when comparing the patients in the observational group who developed visible deformity vs those who did not in: type of fracture (p=0.003), the length of the fracture (p=0.02), the width of fracture (p=0.02), the ratio between the largest width of the fracture and the total width of the fractured orbital floor (p=0.01), dislocated fracture in inferomedial buttress (p=0.04) and area of the fracture (p=0.01). All these significant differences were related to the type of fracture within these two subgroups, see table 2.

Five patients had inferior BOF and 5 patients inferomedial BOF. Of the 6 pa- tients who developed visible deformity, 1 patient had inferior BOF and 5 patients inferomedial wall fractures. Patients with inferomedial BOF had a herniation of 1.6 ml (1.3-4.2). This finding is in line with findings in our results in paper IV, that with inferomedial BOF visible deformity is expected when the herniation is ≥ 0.9 ml (submitted for publication) [78]. One patient with an inferior BOF had a 3.3 cm distance from inferior orbital rim to the posterior edge of the fracture and developed a visible deformity.

Three patients with inferior BOF had a < 3.0 cm distance from inferior orbital rim to the posterior edge of the fracture and did not develop a visible deformity. 1 patient with an inferior BOF had 3.5 cm distance and did not develop visible deformity. This observation is also in line with findings in paper IV (submitted for publication) [78] that with inferior BOF visible deformity is expected when the distance from inferior orbital rim to posterior edge of the fracture is ≥ 3.0 cm.

**Surgical group**
Nine patients had inferior BOF and 7 patients inferomedial BOF. The median volume of the herniation was 2.2 (1.3-3.7) ml and the distance from inferior orbital rim to posterior edge of the fracture was 3.3 (2.6-3.6) mm. For more details about the CT scan findings see table 2.

## VISIBLE DEFORMITY

*Paper III*

**Entrapment and impingement groups**
In one patient with muscle entrapment a 2 mm enophthalmus was found, but this was not observed by the patient. A new evaluation of this patient´s CT scan showed that in addition to her trapdoor fracture in the orbital floor she had a medial BOF which was not reconstructed.

None of the other patients with entrapment or impingement developed visible deformity, either observed by the physician or reported by the patient.

*Paper IV*

Overall, visible deformity (superior sulcus deformity and/or hypoglobus and/or ≥ 3 mm enophthalmus) was found by the physicians in 37% of the patients (n=29) at 2nd (3-7 weeks) or 3rd visit (8-16 weeks) post injury follow ups. Not all patients with visible deformity had enophthalmus, see figure 15.

Twelve patients with 2 mm enophthalmus and six patients with ≥3 mm enopht halmus developed visible superior sulcus deformity and/or hypoglobus. Four patients in each group chose to undergo surgical correction (figure 33). Seven patients with 2 mm enophthalmus did not develop visible deformity.

**Non-operated group**
We found a statistical significant (p<0.001) difference in the position of the eye on ophthalmometry during the study period (figure 45).

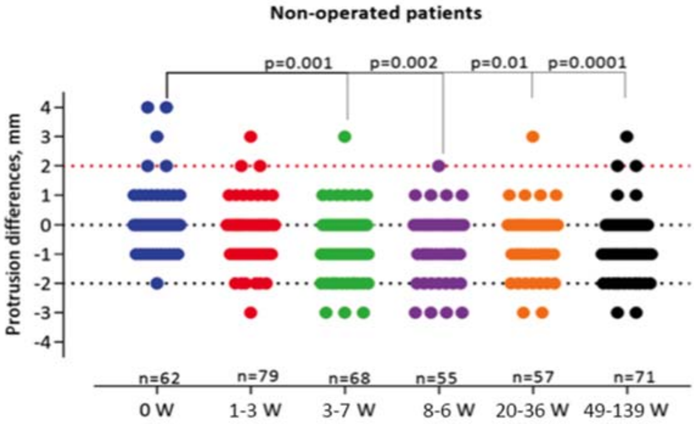



*Figure 45) Scattergram degree of enophthalmus in the non-operated group based on the physicians' findings. The p-values show the significance level between baseline and the different follow up times.*

At the initial examination, the patients presented with exophthalmus or enophthalmus of the injured eye resulting in a median of 0 mm (range +4 to –2). The degree of enophthalmus increased during the study period and the patients were left with a median of 1 mm (range +3 to –3) enophthalmus at the final control. Visible deformity was found by the physicians in 30% (n=21) of the patients, but only 13% (n=9) of the patients reported visible deformity at the final control.

**Operated group**

10% (n=8) of the patients received an operation due to a visible deformity with enophthalmus ≥ 2 mm and/or superior sulcus deformity and/or hypoglobus. The median time from date of injury to surgery was 71 days (31-112). The median degree of enophthalmus among these 8 operated patients was preoperatively 2.6 mm and post operatively at final control 1.0 mm (figure 46), the same as for the patients that were not operated on.

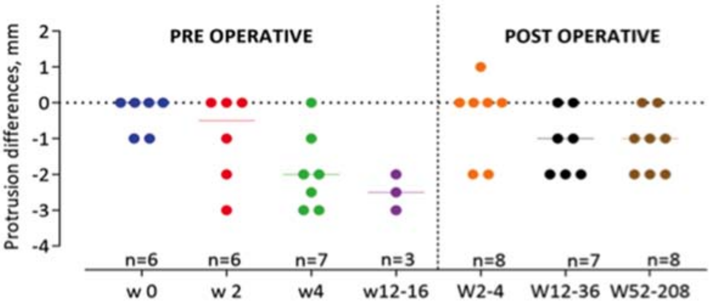



*Figure 46) Scattergram degree of enophthalmus in the operated group, pre- and postoperative, based on the physicians' findings.*

However, there was no statistically significant difference in the degree of enophthalmus at inclusion compared to the final control neither regarding physician's findings nor patients self-report.

All the operated patients (n=8) had a preoperatively visible deformity according to both the physician´s and the patients´ report. Postoperatively at final control, physicians and patients reported visible deformity in 4 cases. But there were congruent opinions only in 2 cases between the physicians´ and patients´ report.

*Paper V*

**Observational group**

Visible deformity (superior sulcus deformity and/or hypoglobus and/or 3 mm enophthalmus) was found by the physicians in 60% (n=6) of the patients, 34 (16-150) days after the injury. 83% (n=5) of the patients with visible deformity had inferomedial BOF and they all chose to proceed with surgery. Surgery was performed 37 (17-170) days after the injury. Visible deformity was resolved in all patients who proceeded. 17% (n=1) of the patients with a visible deformity had an inferior BOF and chose not to undergo surgery.

**Surgical group**

None of the operated patients had a visible deformity at final control. The surgery was performed 13 (3-17) days after injury. In 2 patients, a slightly scleral show was found at the final control and the patients were not interested in surgical correction.

# DISCUSSION

Since the first description of orbital wall fractures by Lang in 1889, who reported on a 13 year old boy with diplopia and enophthalmus after receiving blunt trauma to the eye [79] , management of BOF has been extensively debated. The two aspects that have been considered in this type of fracture have always been function and aesthetics.

In paper II we found extensive discrepancies in the management of BOF with no ocular motility disorder, despite existing recommendations [1, 38, 46]. We found that decision making was based on individual and local traditions and that there were substantial differences in opinions between surgeons, specialties and countries. Our interpretation is that BOF is a complex fracture and that the existing studies in the field are mostly retrospective, often include low number of patients and seldom follow patients long term. Thus, there is a lack of evidence based medicine which normally is an integral part of the clinical decision making process. This causes confusion for both the physician and the patients when deciding on the treatment type.

Evaluation and prediction of late sequelae is based mainly on radiological finding. The radiologists usually only measure the herniated orbital volume by calculating the length x width x height of the herniation. We found that this leads to an underestimation of the herniated volume and to increase the accuracy we have proposed a new method for the calculation. Additionally, other authors have found that there are additional radiological predictors of late visible deformities.

The question is: To operate or not to operate!

# TO OPERATE

**MOTILITY RESTRICTION**

For decades, there has been a consensus that youngsters with orbital trauma who develop acute ocular motility limitation causing diplopia, require immediate surgical intervention (within 24h) due to the hypothesis that delayed surgery is associated with is a high risk for functionally disabling diplopia [42]. In paper II, we confirmed that this consensus is widely followed worldwide. This strongly accepted consensus may to a large extent depend on a study from 1991 by de Man et al [43] who described greenstick fracture in orbital floor in children. Due to children's higher elasticity of the bone, the fracture may result in entrapment of the prolapsed orbital tissue which causes ocular motility limitation [38]. The authors presented one patient, a 12 year old boy with entrapped orbital tissue operated 1 week post injury, where they found histological verified necrotic muscle and fat. Nine months' post injury this patient had some restriction of downward gaze, but no diplopia. They stated that a trapdoor fracture represents an ophthalmologic emergency in need of surgery as soon as possible; otherwise there was a risk for necrosis of the entrapped tissue and residual diplopia [43].

Interestingly, in our series only two patients with entrapment operated day 4 and 5 after the injury, respectively, on examination by the surgeon diplopia was found in extreme upward gaze at the 1 year visit, something that had not bothered the patients in their daily life. In contrast, de Man et al [43], in their series, found that 5 surgically treated children with entrapment had persistent motility impairment to the extent that they needed extra ocular muscle corrective surgery. The time from injury to surgery in these 5 children was similar to what we have described in our study. In our study, we only found one child with entrapment that had ocular motility impairment one week after surgery to the extent that warranted surgical exploration. On re-operation, we found that connective tissue surrounding the inferior rectus muscle remained entrapped. As a consequence our recommendation is that in patients with entrapment of orbital contents it is imperative to be extremely thorough on surgical exploration and in the case of persistent postoperative ocular motility restriction the first option should be surgical re-exploration to ascertain that the entrapped rectus muscle and orbital content are totally reduced. According to our experience small amounts of entrapped tissue may cause motility limitation but may not render a positive force duction test.

When analyzing the group of patients with entrapment, we found no significant differences at the final examination between the 5 patients operated within 24 hours and the 5 patients operated within 48-432h after the injury. This indicates that the importance of immediate surgery and the 24h recommendation to operate on patients with acute muscle entrapment may be debatable. Our interpretation is that surgery is recommended as soon as possible. However, the surgical reduction may be more important than the surgical timing as the release of all the entrapped tissue is crucial for the final result. Therefore, surgery should be delayed until it can be performed by an experienced surgeon.

In paper III we found that adults, 29 (17-77) years old, with an open door type BOF could develop ocular motility limitation due to impingement of periorbital tissue. We found that in such cases, surgical intervention is necessary, but not urgent. In our study the patients recovered from functional symptoms even if operated up to 14 days after the injury. Our interpretation is that a patient with ocular motility restriction causing diplopia due to impingement (not entrapment), is not an ophthalmologic emergency. An ocular motility examination one week post injury is always recommended in patients BOF if impingement is suspected. If there is some improvement, even minor, regular follow-up with appointments with 2-4 week intervals is recommended until this has normalized, may be considered. If the motility limitations and disturbing diplopia remain and no recovery is observed, surgical intervention is recommended. This is a more active approach to patients with suspected impingement than the earlier recommendations to ”wait and see” in patients with BOF who have persisting limitation of ocular movement and diplopia [43], see algorithm.

Patients with entrapment and impingement have diplopia and motility disorder in common. The way to differentiate them from each other is the CT scan finding. In an entrapment case, a BOF is of a trap door type, while impingement is associated with open door BOF.

## ESTHETICALLY VISIBLE DEFORMITY

Even though the human face is notoriously asymmetric, a deformity associated with the eye may be more “eye” catching then other facial deformities [80]. Furthermore, an esthetically visible deformity is a much more subjective variable than diplopia. Therefore, patient and physician may have different opinions on the degree of which visible deformity may be accepted. One of our goals has been to arrive at prognostic factor that enables the surgeon to give the patient an idea of the extent of the visible deformity they may expect with their unique BOF. In this project we have specifically studied CT imaging but other authors may in the future find other predictors of esthetical deformities.

In paper I, we found that relative volume change in the orbit or herniated volume in BOF may be an insufficient criterion for surgery and that prospective studies were needed. In some patients who were considered to have large fractures there was no late visible deformity whereas this was found in some patient with smaller fractures. These confusing results encouraged us to prospectively study a cohort of patients with orbital BOF and to perform a prospective randomized controlled pilot study on patients with orbital BOF, with in total 105 patients included in the two studies that were followed up for at least one year. We found that herniated volume could be used as the only predictor in inferomedial BOF. In inferior BOF, in addition to herniated volume, either the fractured area or the distance from inferior orbital rim to the posterior edge of the fracture seem to be crucial variables in decision making.

According to earlier studies the recommended cut-off points between surgical and non-surgical are changes in the orbital volume [51-53], >1.5 ml herniation [53], increase in cranial- caudal dimension of the orbit > 0.8 cm [54], an orbital floor fracture >1 $cm^2$ [55], >50% fractured orbital floor [50], diplopia 2 weeks after the trauma [50] and an enophthalmus > 2 mm acute or after 6 weeks [55].

It is obvious that not only one but other findings on the CT scan are important when predicting late sequelae. When looking at isolated inferior wall fractures the fundamental cut-off point for the volume of the herniation seem to be 1.0 ml. Interestingly, we found that in fractures < 1.0 ml herniation the area of the fracture seems to be important for the prediction of late visible deformity. In contrast, in fractures with ≥ 1.0 ml of herniation the distance from the orbital rim to the posterior edge of the fracture is crucial. Admittedly, we were surprised by this finding which may explain the clinical finding that some patients with small fractures ultimately develop late visible deformities and some patients with large herniation, where the surgeon expects late sequela, do not. In light of this, the hypothesis of fat atrophy causing deformity in patients with BOF is debatable.

It has been reported that BOF involving both the inferior and medial walls is associated with higher risk for late enophthalmus [56]. Our study confirmed this finding. However, we found a cut-off point at 0.9 ml herniation as a single predictor for the development of late visible deformity, in contrast to inferior wall fractures. Thus, is important to evaluate not only the size of the herniation but the extension of the fracture medially. In our material isolated medial wall fractures were less common and need further studying.

We found that, there is a substantial risk for late visible deformity in patients with (see algorithm):

Inferior BOF with < 1.0 ml herniation and a ratio between fracture and orbital wall areas ≥ 42%, or a fracture area of ≥ 2.3 $cm^2$.

Inferior BOF with ≥ 1.0 ml herniation and a ≥ 3.0 cm distance from inferior orbital rim to the posterior edge of the fracture.

Inferomedial wall fractures with ≥ 0.9 ml of herniation.

We recommend that patients with the above criteria need to be informed about that there is a substantial risk for late visible deformity. For them to understand the extent of the predicted deformity, it is essential that they are shown pictures of patients with different degree of deformity. In this way, the patient can be involved in decision making of the treatment.

In the literature, early surgical intervention in patients with BOF has been proposed to be important for patient outcome [38, 50]. The surgical correction of late posttraumatic enophthalmus has been described to be challenging, with satisfactory results achieved on only 50%-58% of patients [81-83]. In this project, we found that the surgical result from a late correction, when performed immediately on detection by the patient or the surgeon, is similar to that of early surgical corrections. Therefore, in certain patients it may be an option with clinical control at least 1 and 3 months post injury where it is possible to detect and without any delay address a detected deformity. Furthermore, by waiting the traumatic orbital edema will decrease which is beneficial for surgical reconstruction.

Thus, in our opinion, the aesthetic end result is not dependent on how early you operate. Using this approach the surgeon will avoid operating on patients that may tolerate minor visible deformities. A part from making the patient satisfied, saving the psychological stress the patient is exposed to by performed surgery and also the socio-economical impact an over treatment has.

**NOT TO OPERATE**

Our understanding is that there may be a substantial number of patients that are unnecessarily operated due to the lack of international consensus based on prospective studies on functional impairment and late visible deformity predictors.

Conditions that endanger the vision, such as hyphema, lacerated globe etc., may be a contraindication to surgical intervention. However, other ophthalmologic conditions such as traumatic iritis, traumatic mydriasis and commotio retinae are not contraindications to BOF reconstruction, if needed [47]. Therefore, an ophthalmologist consultation is of high value.

Some patients, especially those elderlies may live with some degree of orbital deformity rather than the risks anesthesia may cause or the surgical complications which have been reported to be up to 20% [57, 58]. Surgery in a patient´s only seeing eye to prevent from visible deformity is obviously not recommended, but disabling ocular motility restriction may be surgical indication.

Almost all of the patients with BOF have diplopia which often improves within 2 weeks after the injury [34]. Persistent diplopia with no ocular motility limitation has been suggested as a surgical indication in BOF [46], while other authors have reported spontaneous recovery of diplopia 1 year after injury [49]. In this project, we found that it will to great extent resolve over time (only 5% had limited diplopia at final visit), unless there was ocular motility restriction. Thus, our understanding is that diplopia in itself is not a surgical indication.

The statement that, late enophthalmus will lead to diplopia [84] could not supported in this project. On contrary, none of the patients with late enophthalmus had diplopia and none of patients with diplopia had enophthalmus. It has been reported that over time patients' binocular fusion mechanism adjust itself to the displacement of the globe, and the cosmetic deformity was not an important issue [85].

In our study we found that some patients developed visible deformity without been aware of it. When the patients were informed about the deformity, not all of them were interested in surgical treatment. Patients were mainly happy that they had gradually got relief of diplopia which has also been reported earlier [86].

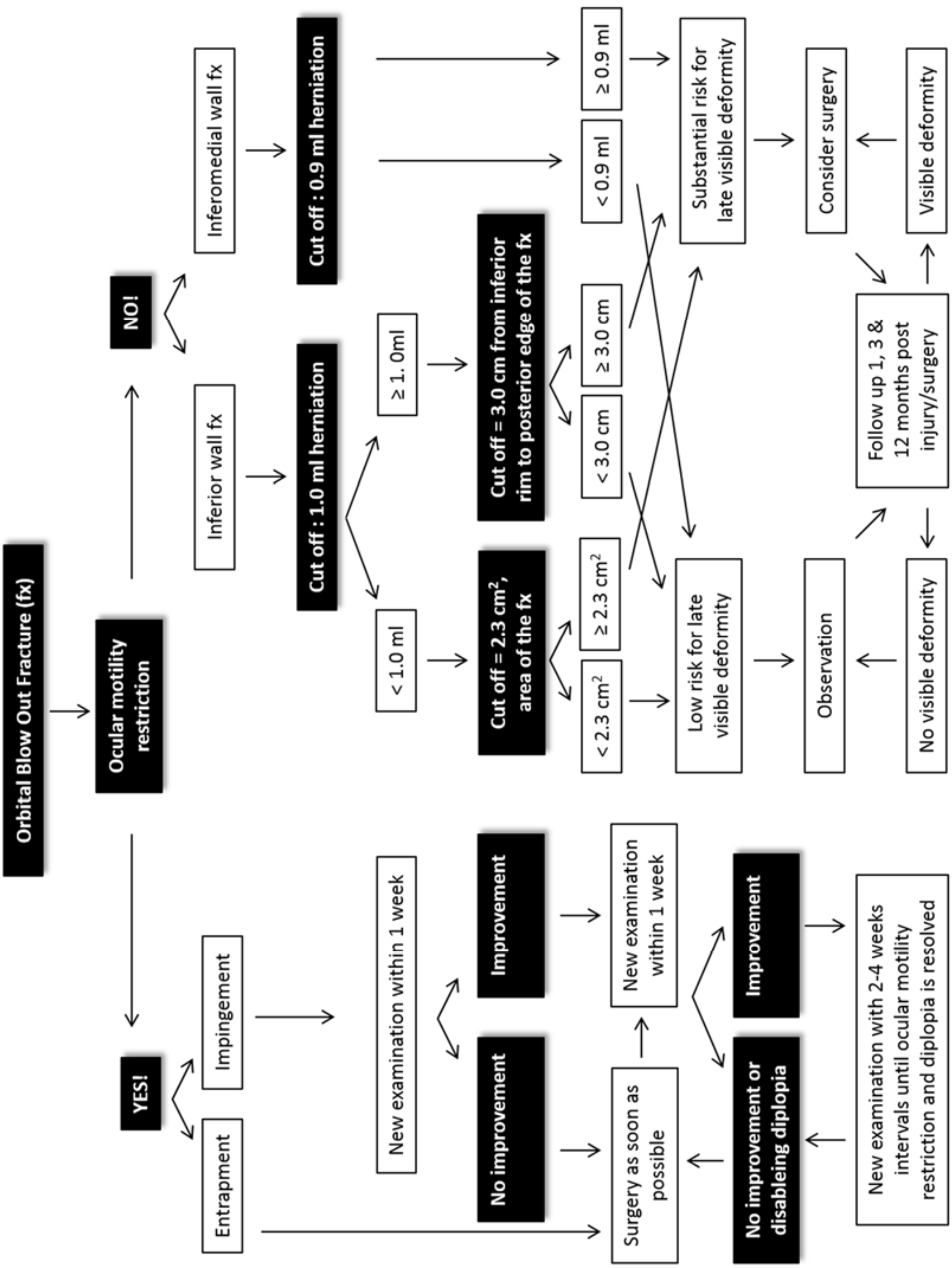
We found that hypesthesia improved over time but remained in 18% of patients in non-operated patients. It is important to recognize that surgery does not improve hypesthesia but rather that it may be a complication to surgical reconstruction which we also confirmed in our study.

Therefore, it is crucial that no patient should undergo surgery if it not needed as not only the development of hypesthesia but late visible deformities such as scleral show, entropion and ectropion is associated with surgical intervention. Furthermore, acute and sub acute surgical complications, bleeding and postoperative infection, should also be considered. It is not hard to conclude that apparently, some patients undergo surgical unnecessarily, when the surgeons believe that they are helping the patient with repairing the orbit.

We believe that surgery is not indicated:

- When diplopia is not caused by ocular motility restriction.
- In hypesthesia of the infraorbital nerve.
- In a patient´s only seeing eye, unless there is disabling motility restriction.
- If there is hyphema or laceration of the globe.

Algorithm. Management of Orbital Blow Out Fracture.



# SUMMARY

When deciding on to operate or not in patients with BOF it is important to recognize that surgical indications upon functional impairment is limited to muscle motility restriction due to entrapment or impingement. Other functional impairment is generally benign and will resolve over time. Regarding late visible deformity development patient involvement in decision making is crucial since patient experience of the importance of facial asymmetry is individual and may differ from the surgeons' opinion.

# CONCLUSIONS

## PAPER I

The herniated orbital volume in BOF alone, may be an insufficient criterion for surgery.

- The relative volume change between the fractured and non-fractured orbit in an individual does not appear to be a useful criterion for surgery.

## PAPER II

- There is a clear agreement that a BOF with ocular motility limitation needs surgery within hours and that there is little or no risk for late enophthalmus in such a case.
- There are considerable differences in opinion regarding the management of BOF (with no ocular motility limitation) between surgeons, specialties and countries.

## PAPER III

- We did not find any significant correlation between the time from injury to surgery and the outcomes in ocular motility and diplopia.
- Diplopia due to ocular motility restriction caused by entrapment, requires surgery as soon as possible, but performed by an experienced surgeon.
- Diplopia due to ocular motility restriction caused by impingement is not an ophthalmologic emergency and surgery is recommended if the diplopia and ocular motility is not improved over time.
- The surgical reduction is at least as important as surgical timing for the outcome.

## PAPER IV AND V

- BOF patients with following CT scan findings developed cosmetic problems:
  - Isolated inferior wall fracture with a herniation < 1.0 ml and a fracture area ≥ 2.3 cm$^2$.
  - Isolated inferior wall fracture with a herniation ≥ 1.0 ml and a fracture distance from inferior orbital rim to the posterior edge of the fracture ≥ 3.0 cm.
  - Inferomedial fracture with a herniation ≥ 0.9 ml.
- Hypesthesia of inferior orbital nerve may remain and surgery may increase the risk for development of hypesthesia.
- Diplopia in BOF, without motility limitation, is due to edema and it is not an indication for surgery.
- Late correction of BOF appears to have the same outcome as early corrections if the surgical correction is performed immediately after the visible deformity is discovered. This require though a close follow up of the patient, as a suggestion 1 and 3 months post injury.

# APPENDIX

## THE MEASUREMENT OF THE ORBITAL VOLUME PAPER I

Starting on the uninjured side on the axial CT slices, the optic nerve in the orbital channel was centered at its thickest (Fig. 3). The optic nerve's exit from the eye globe was marked with the cursor/red point as Point 1 (Figure 19). In ''Oblique'' with a Fixing Point 1 as the center, the foramen opticus on both sides were centralized as widest. The lateral edge of the superior orbital fissure on the uninjured side was marked as Point 2 and the same structure on the contralateral side was marked as Point 3 (Figure 19). Points 1, 2, and 3 together constituted a fixing platform during the rest of the volume calculation. The posterior border was defined by eliminating the structures behind the line between the Points 2 and 3 (Figure 19). To define the anterior border, in the same plane, the picture was scrolled to its widest and most distinct point of the lacrimal channel bilaterally and marked as Points A1 and A2 (Figure 20). The lateral orbital limits were marked bilaterally as Points B1 and B2 (Figure 20). The anterior borders were formed by eliminating the structures anterior to A1-B1 and A2-B2 (Figure 20). The volume of the orbital content was then measured by using the VR tools. Starting on the uninjured orbit on an axial slice cranially, the following steps were taken: clicking on

''VR tools''; ''Add structure''; ''Clear Destination''; the orbital content was marked with the mouse and left-clicked so that the area of interest was colored green. Then the slice was scrolled three to four steps caudally and the same procedure was performed until all the orbital content of interest was colored green. If any structure of no interest was colored green by mistake, the ''Remove Structure'' key was selected, and the areas were marked with the mouse by clicking the left button. When the axial slices were completed, we moved to the coronal and then to sagittal slices and the same procedure was repeated (Figure 47).

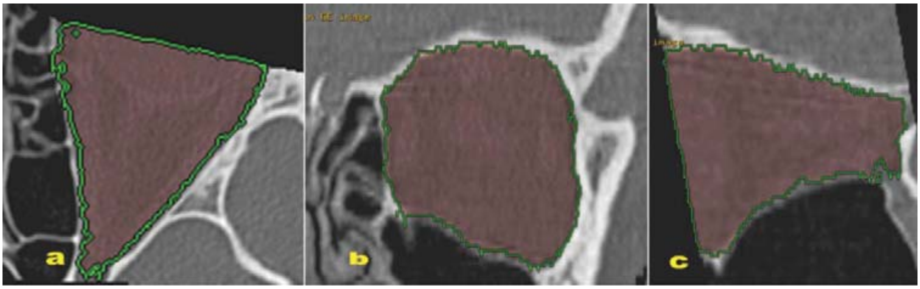



*Figure 47. Content of the orbit marked for the volume measurement: (A) axial slide, (B) coronal slide, (C) sagittal slide.*

To see the volume of the marked orbital content, ''Display Tools'' was clicked; the ''Globe'' key was selected and the marked orbital content was clicked. To exclude the bone structure, which may have been added, the ''Threshold'' was set between 0 and 200. Then by clicking on ''Apply,'' the volume of the orbital appeared on the screen (Figure 48).

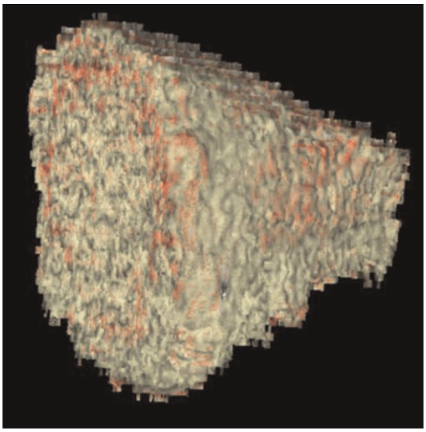


*Figure 48. The orbital volume.*

To calculate the content of the other orbit, the ‘‘Apply’’ key was clicked, then ‘‘Undo Apply T’’; ‘‘3D tools’’; ‘‘Auto Select’’; ‘‘Clear Destination’’ before repeating the same steps to measure the contralateral orbit content. The volume of herniated orbital soft tissue was measured as follows. The herniated orbital soft tissue was defined as orbital tissue herniated from the fracture edges of the orbital floor into the maxillary sinus. The hematoma underneath the herniated orbital soft tissue in the maxillary sinus was not included. The volume of the herniated orbital soft tissue was then measured by using the VR tools. Starting on the coronal slices, the herniated orbital soft tissue was marked anteriorly, and the following steps were taken: clicking on ‘‘VR tools’’; ‘‘Add structure’’; ‘‘Clear Destination’’; the orbital content was marked with the mouse and left-clicked so that the area of interest was colored green. Then the slice was scrolled three to four steps posteriorly, and the same procedure was performed until all the orbital content of interest was colored green. If any structure of no interest, for example, hematoma, was colored green by mistake, the ‘‘Remove Structure’’ key was selected and the areas were marked with the mouse by clicking the left button (Figure 17). When the coronal slices were completed, we moved to the axial and sagittal slices and the same procedure was repeated. To see the volume of the marked orbital content, ‘‘Display Tools’’ was clicked; the ‘‘Globe’’ key was selected, and the marked orbital content was clicked. To exclude the bone structure, which may have been added, the ‘‘Threshold’’ was set between 0 and 200.

# PATENTS ´SELF-REPORTED QUESTIONAIRE

*Patients´ self-reported questionnaire*

Number in the study: ……  Birthday: ……………  Initials:.......  Age at injury: ……

Male ☐  Female ☐  Fractured orbit: Right ☐  Left ☐

Operated: Yes ☐  NO ☐

Date: ………………

| Questions | Answers |
|---|---|
| 1. Is your injured eye sunken in? | Yes ☐ NO☐ |
| 2. Do you have double vision? If yes, in which direction? | Yes ☐ No ☐<br>Up ☐ Down ☐ L☐ R☐ Straight ☐ |
| 3. Do you have desensibility in your face due to the injury? | Yes ☐ No ☐ |
| 4. Are you happy with how your fracture has been treated? If not, what aren´t you happy with? | Yes ☐ No ☐<br>Comment: |

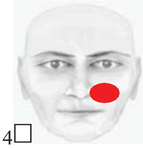
# PHYSICIANS´ PROTOCOL ON CLINICAL EXAMINATION

*Physicians´ protocol on clinical examination*

Number in the study: …… Birthday: …………… Initials: ....... Age at injury: ……

Male ☐ Female ☐ Fractured orbit: R ☐ L ☐ Operated: Yes ☐ NO ☐

Date of: Injury ………… Inclusion ………… Surgery: …………… Date: ……………….

| Questions | Answers |
|---|---|
| 1. Visible En/exophthalmus on the injued eye? | Exophthalmus: Yes ☐ No ☐ Not judgable ☐<br>Endophthalmus: Yes ☐ No ☐ Not judgable ☐ |
| 2. Visible hypo/hyperglobus on the injured eye? | Hyperglobus: Yes ☐ No ☐ Not judgable ☐<br>Hypoglobus: Yes ☐ No ☐ Not judgable ☐<br>☐ |
| 3. If double vision, in which direction? | Up ☐,Down ☐ ,left ☐ ,Right ☐ ,Straight ☐<br>No double vision ☐ |
| 4. Motility restriction of the injured eye? If yes: in which direction? | Up ☐ ,Down ☐,Left ☐ ,Right ☐ ,Straight ☐<br>No motility restriction ☐ |
| 5. Hypesthesia of the inferaorbital nerve on the fractured side?<br>1. No hypesthesia, 2. Alar area 3. Upper lip 4. Cheek 5. The upper teeth<br> 1 ☐  2 ☐  3 ☐  4 ☐  5 ☐ | |
| 5. Exoftalmometry according Hertel.<br><br>Not measureable: ☐ | Mesurement 1: R: ….. L: ….. Diff: …..<br>Mesurement 2: R: ….. L: …..<br>Mesurement 3: R: ….. L: ….. Base: …. |
| 6. Superior sulcus deformity? | Yes ☐ No ☐ |

# POPULÄRVETENSKAPLIG SVENSK SAMMANFATTNING

När ett öga utsätts för allvarligt trubbigt våld kan ögat tryckas in i ögonhålan. Som en skyddsmekanism för att förhindra ögat från att spricka, uppstår en fraktur i ögonhålans tunna väggar. En sådan fraktur kallas Blow Out Fracture (BOF). Det är vedertaget att en omfattande BOF behöver kirurgisk behandling då det annars kan leda till dubbelseende och estetiska deformiteter, som insjunket öga (enoftalmus). En liten BOF behöver dock inte någon kirurgisk korrektion, utan den kommer att läka av sig själv utan några kvarvarande symtom. Därför är det viktigt att kunna bedöma om en patient behöver opereras eller inte. Detta har varit föremål för flera studier i årtionden.

Det övergripande syftet med denna avhandling har varit att identifiera vilka patienter med BOF som behöver opereras, eller inte opereras, med tanke på risken för funktionella och estetiska besvär.

I delarbete I fann vi att volymen av vävnad i ögonhålan som i samband med en BOF kan tryckas ner i käkhålan, så kallad herniering (bråckbildning) och den relativa volymsförändringen som uppstår mellan den friska och skadade ögonhålan inte är tillförlitliga redskap att använda för att bedöma om en patient behöver kirurgisk behandling eller inte.

I delarbete II kom vi fram till att det finns en enhetlig konsensus om att kirurgi inom 24 timmar behövs när ögats rörlighet är nedsatt, till följd av inklämning av ögonmuskler i frakturen efter trauma mot ögat. När det gäller hanteringen av resterande BOF fann vi stora meningsskiljaktigheter mellan kirurgerna, specialiteterna och länderna, trots befintligarekommendationer.

I artikel III fann vi att vid nedsatt ögonrörlighet, till följd av inklämning av ögonmuskel i frakturen, finns det behov av kirurgisk behandling. Denna ska utföras av en erfaren kirurg så snart som möjligt, men inte nödvändigtvis inom 24 timmar. Vidare konstaterade vi att vid nedsatt ögonrörlighet till följd av upphakning av ögonmuskler i frakturen (inte inklämning), finns det inte behov av akut kirurgisk behandling. I ett sådant fall rekommenderas kirurgi om dubbelseende och ögonrörligheten inte förbättras alls efter en vecka. Vi fann också att noggrann korrektion av frakturen är viktigare för slutresultatet än hur snart efter skadan en kirurgisk behandling kan ske.

I delarbete IV-V utförde vi prospektiva kohort och kontrollerade randomiserade studier på patienter med BOF. Vi fann signifikant skillnad mellan de patienter som utvecklade kosmetisk deformitet och de som inte utvecklade kosmetisk deformitet, då vi undersökte olika parametrar baserade på datortomografi. Vi kunde dra slutsatsen att BOF-patienter med följande parametrar har stor risk för att utveckla kosmetisk deformitet och att kirurgisk behandling bör övervägas:

- Isolerad inferior väggfraktur med < 1.0 ml herniering och en frakturarea ≥ 2.3 $cm^2$,
- Isolerad inferior väggfraktur med ≥ 1.0 ml herniering och ett avstånd från nedre ögonhålekanten till den bakre kanten av frakturen ≥ 3.0 cm.
- Inferomedial fraktur med en herniering ≥ 0.9 ml.

Vi fann också att dubbelseende i samband med BOF, utan påverkan på ögonrörligheten, beror på svullnad och att detta inte är en indikation för kirurgi. Påståendet att enoftalmus leder till dubbelseende kunde inte bekräftas av våra data. Tvärtom, ingen av de patienter som utvecklade enoftalmus hade dubbelseende; och ingen av de patienter med dubbelseende hade enoftalmus.
Vidare fann vi att fördröjd kirurgisk korrektion av BOF verkar ha samma slutresultat som en tidig korrektion, om kirurgin utförs omedelbart efter det att en kosmetisk deformitet upptäcks. Detta kräver dock en tät uppföljning av patienterna - förslagsvis 1 och 3 månader efter skadan.
I detta projekt har vi arbetat fram en algoritm baserad på tillförlitliga data för att förutse vilka patienter med BOF som har nytta av kirurgisk behandling.
Sammanfattningsvis visar denna avhandling att vid beslutstagande om kirurgisk behandling, är det viktigt att känna till att kirurgi på grund av funktionella besvär är begränsade till nedsatt ögonrörlighet till följd av inklämning eller upphakning av ögonmuskel i frakturen. Resterande funktionella besvär är benigna och minskar med tiden. Beträffande beslutstagande om kirurgisk behandling på grund av kosmetisk deformitet, är det viktigt med patientens egen uppfattning om deformitetens betydelse, eftersom vikten av en deformitet är individuell och den kan skilja sig från kirurgens uppfattning.

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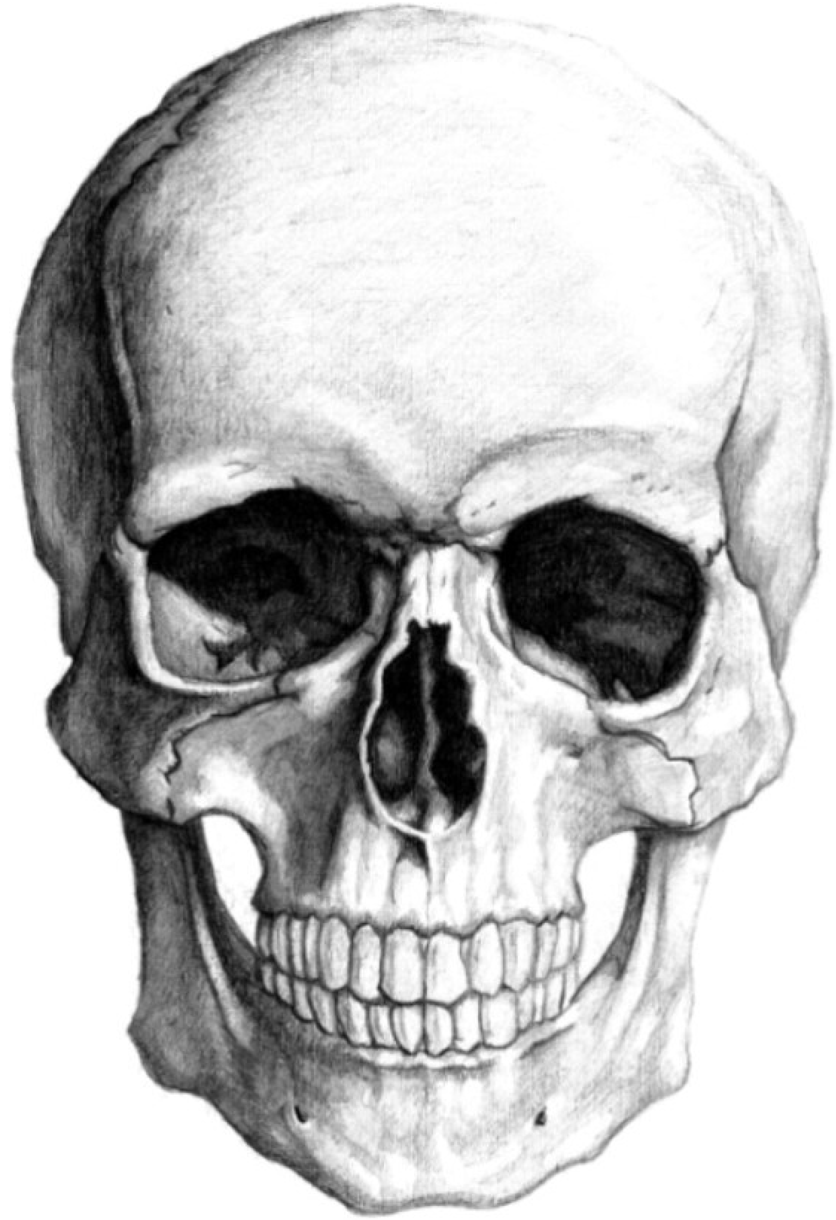

# Relative Difference in Orbital Volume as an Indication for Surgical Reconstruction in Isolated Orbital Floor Fractures

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## ABSTRACT

In orbital floor fractures, the estimation of the herniated orbital content in the maxillary sinus has traditionally been the dividing line between surgical and nonsurgical management. In this study, we evaluated whether a relative change in volume would function as an indicator for surgical versus nonsurgical treatment of orbital floor fractures. This was a follow-up study in patients with untreated unilateral isolated orbital floor fractures admitted to our department from March 2003 to April 2007. Patients were contacted by regular mail and invited to have a clinical eye examination. The volume of the orbital content was calculated digitally from the patients' computed tomography scans at the time of their injury. Eighteen subjects with no facial skeleton fracture were included for reference of orbital content volumes. Five of 23 patients showed 2 to 4 mm of enophthalmos, and only three of them had intermittent diplopia. No statistical correlation was found between the herniated volume and enophthalmos. No statistical correlation supporting the supposition that 1 mL of herniated orbital content would result in 1 mm of enophthalmos was found. The relative volume change between the fractured and non-fractured orbit in an individual does not appear to be a useful criterion for surgery. The importance of the herniated orbital tissue for the development of enophthalmos is unclear.

**KEYWORDS:** Orbital floor fracture, blowout fracture, orbital volume, nonsurgical treatment

Fractures involving the orbit are very common in the emergency room. Isolated fractures of the orbital floor are often referred to as a *blowout fracture* (BOF). Post-traumatic enophthalmos is a well-known sequel that is considered to be related to changes in orbital volume.[1–4] In some cases, the orbital floor fragments are not displaced, and the orbital volume remains unchanged. If there are no other indications for surgery (disturbing double vision, entrapped inferior rectus muscle, or obvious enophthalmos), such a fracture may be left without

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surgical intervention. However, a BOF usually causes an extensive displacement of bone fragments resulting in an expansion of orbital content into the underlying maxillary sinus (i.e., herniation[5]). A surgical intervention with reconstruction of the orbital floor has been considered to be necessary by some authors to restore orbital volume and reposition the eye bulb.[1,2] A dividing line between surgical and nonsurgical management traditionally has been the estimated volume of the herniated orbital content into the maxillary sinus.[2] Thus, it is mentioned that a 0.8- to 1-$cm^3$ herniation will result in an enophthalmos of 1 mm.[2,6] Accordingly, a 1.6- to 2-$cm^3$ herniation will result in a 2-mm enophthalmos.[7] Such volume estimations are made from computed tomography (CT).[8,9]

In the nonherniated and the severely herniated cases, treatment is not debated. Generally, a herniation with a volume of $>1.5$ $cm^3$ is considered to be an indication for surgical reconstruction of the orbital floor.[1] However, even in these cases evidence from randomized controlled studies is lacking. Clinically, the problematic cases are those with a herniation just less than 1.5 $cm^3$ where the risk of surgical sequelae arising[10] has to be evaluated against the risk of the patient developing posttraumatic enophthalmos,[1,4,11,12] if the fracture is left unoperated. Another important question in orbital floor fractures is whether pure volume change is a proper indication for surgery.[13] One cubic millimeter herniation in a large person may be quite different than a similar herniation in a smaller person, if the herniation volume is compared with the total orbital volume.[14]

The aims of the present study were twofold: partly to evaluate whether the decision to refrain from surgery based on a herniated volume of $<1.5$ $cm^3$ in a series of patients was correct, and partly to evaluate whether the relative change in orbital volume would be a better indicator for surgical versus nonsurgical treatment of BOF. Furthermore, we introduce a new method of calculating orbital volume and herniation.

## MATERIALS AND METHODS

From the patient records in the Ear, Nose, and Throat department at the Karolinska University Hospital, patients were selected who had an isolated, untreated unilateral fracture of the orbital floor, diagnosed using a CT scan. The decision to refrain from surgery of the orbital floor fracture had been taken on the basis of the volume of the herniated orbital content, usually between 1.0 and 1.5 mL. From March 2003 to April 2007, 89 patients had met these criteria. They were all contacted by regular mail. In the letter, they were invited to have a clinical eye examination at the St. Erik Eye Hospital in Stockholm, Sweden. A control group of 18 subjects who had undergone CT examination of the facial skeleton for reasons other than orbital fracture were included for reference. The study was approved by the Local Ethics Committee at the Karolinska Institute.

**Figure 1** The volume of the herniated orbital content.

The patients reported their impression of the eye bulb position and the presence of double vision or symptoms related to their eyes and vision. The clinical examination included an examination for diplopia and measurement of enophthalmos according to Hertel.[15]

The volume of the orbital content was calculated digitally from the patients' CT scans at the time of their injury. The CT scans used $\leq$2-mm slices. On the fractured side, the volume (in milliliters) of the herniation (Fig. 1) and the volume of the orbit including the herniation (Fig. 2) were measured. The herniated orbital soft tissue was defined as the displaced orbital content, including orbital fat and muscle, truly herniating through the fracture of the orbital floor into the maxillary sinus, excluded the hematoma. The orbital volume on the nonfractured side was also measured for calculating the relative volume difference. The orbital volumes

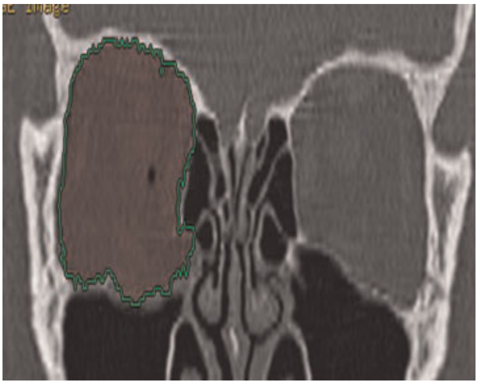

**Figure 2** Volume of the orbital content including the herniated orbital volume.

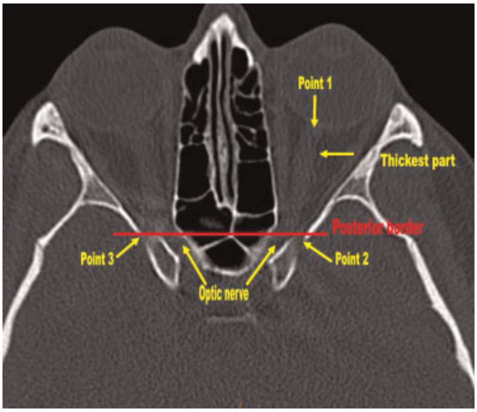


**Figure 3** The posterior border in orbital volume measurements. Point 1, the exit of the optic nerve from the eye globe. Points 2 and 3 are the lateral edges of the superior orbital fissure on each side.

of the control group, who had no previous facial fractures, were measured using the same method described. These measurements were used to estimate the individual variability of orbital volumes in normal individuals.

To facilitate repetitive volume measurements, a standardized method of defining the orbital borders was created by defining three distinct anatomic landmarks on the CT scan. These were: (1) posterior—in the central portion of the optic nerve at the level of the lateral edge of the superior orbital fissure (Fig. 3); (2) anterior/nasal—the most distinct and widest laterodorsal duct of the lacrimal canal bilaterally (Fig. 4); (3) anterior/temporal—the most anterior portion of the lateral orbital limit (Fig. 4). The volume of the orbit was calculated craniocaudally inside the bony orbital borders within these three points. (See Appendix for details.)

CT images were all entered into a GE Healthcare Advantage Workstation version 4 (GE Healthcare, Milwaukee, WI). The orbital volume was measured with the rendering software in the Volume Viewer version 2.0 (GE Healthcare). (See Appendix for details.)

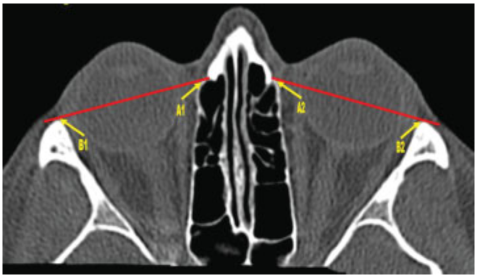


**Figure 4** The anterior border in the orbital volume measurements. A1 and A2, the most distinct and widest laterodorsal duct of the lacrimal canal; B1 and B2, the lateral orbit limit.


**Figure 5** Sagittal computed tomography slice where the fracture is considered largest. (A) Infraorbital margin, (B) anterior, and (C) the posterior part of the fracture.

The localization of the fracture was measured on the sagittal CT slice where the fracture was considered largest. The distance from the infraorbital margin to the anterior and the posterior part of the fracture was measured (Fig. 5).

The data were organized in MS Excel and analyzed with the StatSoft, Inc. (2007) STATISTICA data analysis software system, version 8.0 (www.statsoft.com). A correlation analysis was performed on the orbital measurements and the ophthalmologic data to determine the coefficient of determination ($r^2$). To evaluate the reproducibility of the measured orbital volumes, two people separately calculated the orbital volumes using the same method. The intraclass correlation coefficient (ICC) was derived from a two-way mixed-effects model.

## RESULTS

Eighty-nine patients were contacted and 43 (48%) responded. Twenty of those were excluded: two appeared to have had a medial orbital wall fracture instead of an orbital floor fracture, and 12 had been scanned with CT slices thicker than 2 mm. Finally, six individuals did not show up for the examination. Thus, 23 individuals were included in the study. There were 19 men and 4 women. They had a mean age of 41 (17 to 74). The mean time from injury to examination was 22 months (6 to 46). The CT scans of the patients were performed within 1.9 days[1,2,5–8,10] after the injury.

The mean herniated volume was 1.0 mL (0.2 to 2.2). The relative volume difference between the fractured and the nonfractured orbit was 1.4 mL (0 to 3.4) or in percentage terms 8.6% (0 to 18.7%; Table 1). The

**Table 1 Summary of Clinical and CT Scan Findings**

| Patient | Diplopia | Note to Diplopia | Enophthalmos (mm) | Herniated Volume (mL) | Relative Orbital Volume Difference (%) | The Distance from Infraorbital Margin to the Posterior Part of the Fracture |
|---|---|---|---|---|---|---|
| 1 | No | | No | 0.4 | 9.8 | 15.5 |
| 2 | No | | 1 | 0.2 | 9.9 | 18.3 |
| 3 | No | | No | 1 | 12.5 | 21.8 |
| 4 | No | | No | 0.2 | 0 | 23.9 |
| 5 | No | | No | 1.2 | 0.4 | 24.1 |
| 6 | Yes | Pretrauma | 2 | 0.3 | 8.5 | 20.2 |
| 7 | No | | No | 1.1 | 6 | 21.5 |
| 8 | No | | 1 | 0.2 | 3.5 | 29.1 |
| 9 | Yes | Posttrauma | 2 | 1 | 0.5 | 24.3 |
| 10 | No | | No | 0.2 | 0.05 | 22.4 |
| 11 | Yes | Pretrauma | No | 1.7 | 0.5 | 23.3 |
| 12 | No | | No | 2 | 11.8 | 27.3 |
| 13 | Yes | Posttrauma | 1 | 1.7 | 11.4 | 29.3 |
| 14 | No | | 2 | 1.7 | 2.7 | 27.6 |
| 15 | No | | 2 | 2.2 | 10.7 | 31.8 |
| 16 | No | | No | 0.5 | 18.7 | 20.6 |
| 17 | No | | No | 1.1 | 1.6 | 24.1 |
| 18 | No | | No | 0.6 | 7.8 | 20.8 |
| 19 | Yes | Posttrauma | 4 | 1.5 | 9.6 | 35 |
| 20 | Yes | Pretrauma | No | 1 | 17.2 | 32 |
| 21 | Yes | Pretrauma | No | 1.6 | 14.9 | 26 |
| 22 | No | | 1 | 1 | 4.2 | 16.9 |
| 23 | Yes | Posttrauma | No | 1 | 1.5 | 20.7 |

CT, computed tomography.

corresponding relative mean volume difference in the control group was 0.6 mL (0.1 to 1.4) and 2.5% (0.5 to 6.1%; Table 2). The correlation between herniated orbital volume and the relative orbital volume difference between orbits was found to be poor (Fig. 6). The relative difference in orbital volumes were significantly different between the two groups ($p = 0.049$; Mann-Whitney $U$ test).

The analysis of the reproducibility of the orbital volume measurements by the two investigators revealed a mean value of the differences between the operators as 0.259 (standard deviation 1.397). The ICC, evaluated by a two-way mixed-effects model, was 0.822 (95% confidence interval from 0.700 to 0.898; Fig. 7).

Five of the 23 patients presented with an enophthalmos mean of 2 mm.[2,5,6] The mean herniated volume in these cases was 1.3 mL (0.3 to 2.2). There was no correlation between the herniated volume and the degree of enophthalmos ($r^2$ value; Fig. 8). We did not find that large relative changes in orbital volume in orbital fractures correlated with posttraumatic enophthalmos (Fig. 9). Eight patients experienced an intermittent diplopia, and four of those could be related to their orbital floor fracture. For details, see Table 1.

The mean distance from the infraorbital margin to the anterior part of the fracture was 7.8 mm (2.0 to

**Table 2 Orbital Volumes of the Control Group**

| Right Orbit (mL) | Left Orbit (mL) | Orbital Difference (%) |
|---|---|---|
| 21.3 | 22.7 | 6.6 |
| 20.6 | 20.2 | 2.0 |
| 19.5 | 19.7 | 1.0 |
| 21.0 | 21.3 | 1.4 |
| 21.0 | 21.3 | 1.4 |
| 19.2 | 18.9 | 1.6 |
| 22.0 | 21.7 | 1.4 |
| 22.0 | 21.7 | 1.4 |
| 19.3 | 20.3 | 5.2 |
| 21.1 | 20.9 | 1.0 |
| 24.7 | 25.6 | 3.6 |
| 23.8 | 22.5 | 5.8 |
| 19.6 | 20.0 | 2.0 |
| 21.0 | 20.8 | 1.0 |
| 20.1 | 20.9 | 4.0 |
| 20.2 | 20.8 | 3.0 |
| 17.7 | 18.6 | 5.1 |
| 19.8 | 19.7 | 0.5 |

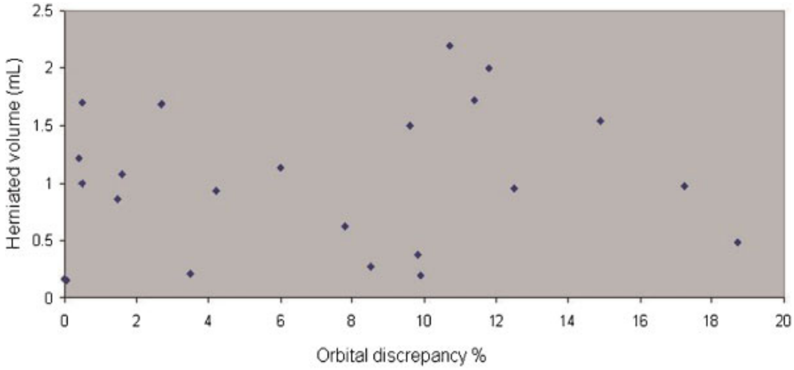


**Figure 6** Orbital discrepancy % ($x$) by herniated volume mL ($y$).

17.1) and to the posterior part of the fracture, 23.0 mm (16.9 to 35.0). A correlation analysis of the orbital volume ($y$) of the fractured orbit and the localization of the fracture ($x$) was performed that showed a weak ($r^2 = 0.25$) but significantly ($p < 0.001$) increased risk of larger herniation in fractures that extend more posteriorly (Fig. 10). One plausible explanation for this might be that the distance from margo to the posterior location of the fractures is longer in larger orbits ($r^2 = 0.30$; $p < 0.01$). The longer and larger an orbit is, the more likely to lead to a larger herniation. Two measurements (in millimeters) of the fracture localization were evaluated from the CT scan (i.e., the distance from the margin to the anterior and the posterior part of the fracture; Table 1). The analysis revealed a positive correlation between the orbital volume and the posterior localization of the fracture ($r^2 = 0.50$; $p < 0.05$). Two of five patients with enophthalmos had posteriorly extended fractures 31.8 and 35.0 mm (Fig. 11). Only one patient (No. 19) in the study group was cosmetically discomforted by the enophthalmos, which measured 4 mm.

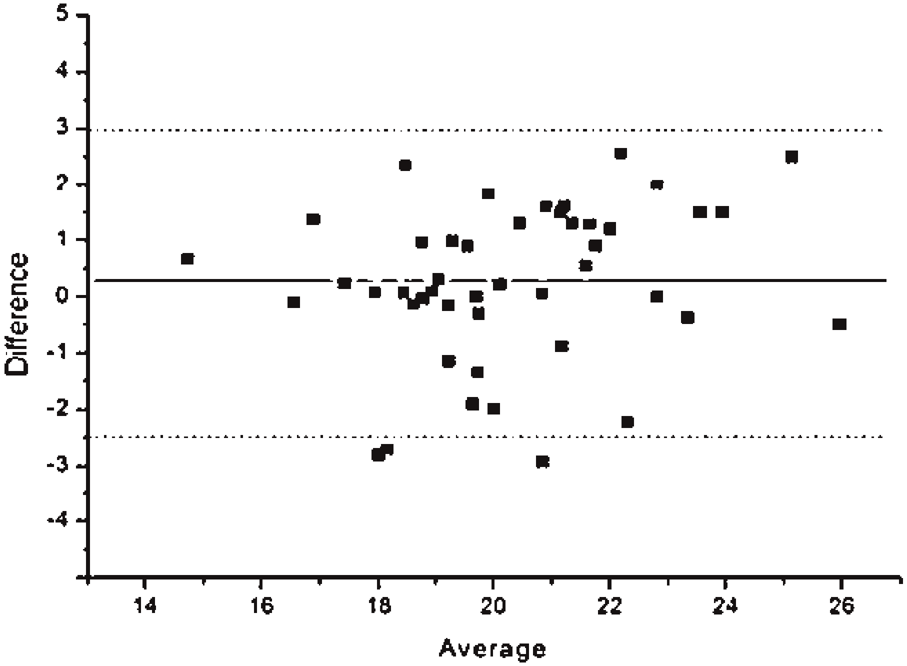


**Figure 7** The analysis of the reproducibility of the orbital volume measurements. Mean value of the differences between the operators was 0.259 (standard deviation 1.397).

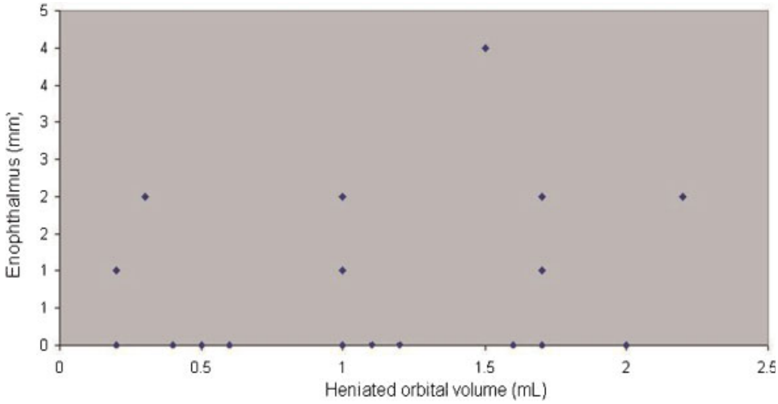


**Figure 8** Herniated orbital volume ($x$) by enophthalmos ($y$).

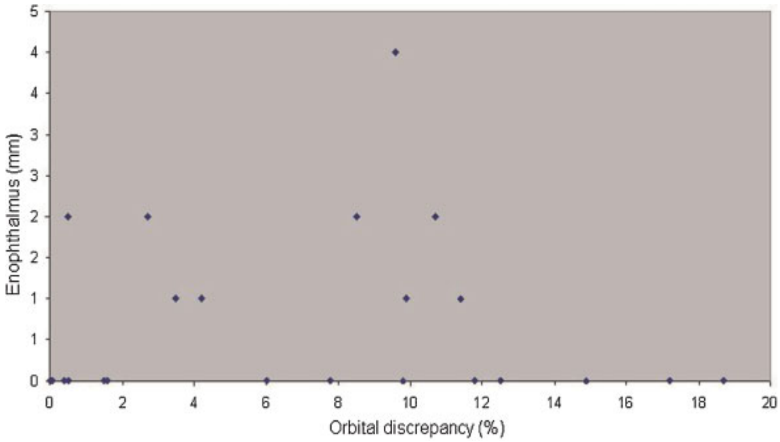


**Figure 9** Orbital discrepancy ($x$) by enophthalmos ($y$).

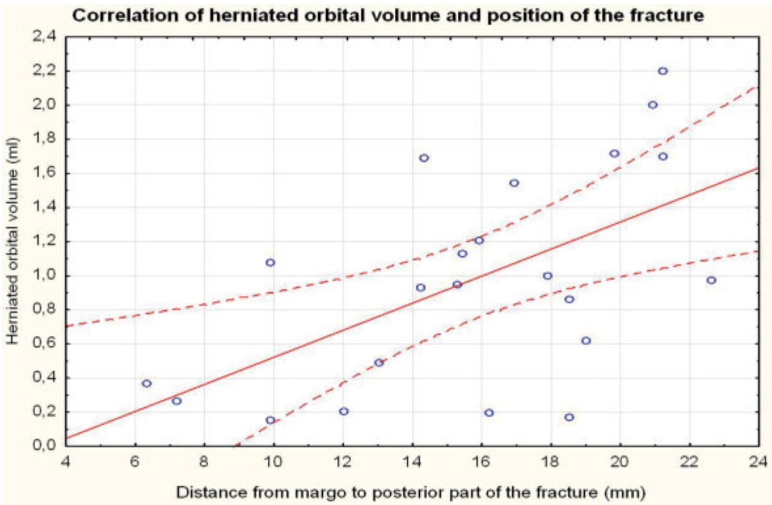


**Figure 10** Correlation of herniated orbital volume and position of the fracture. Distance from margo to posterior part of the fracture ($x$) by herniated orbital volume ($y$).

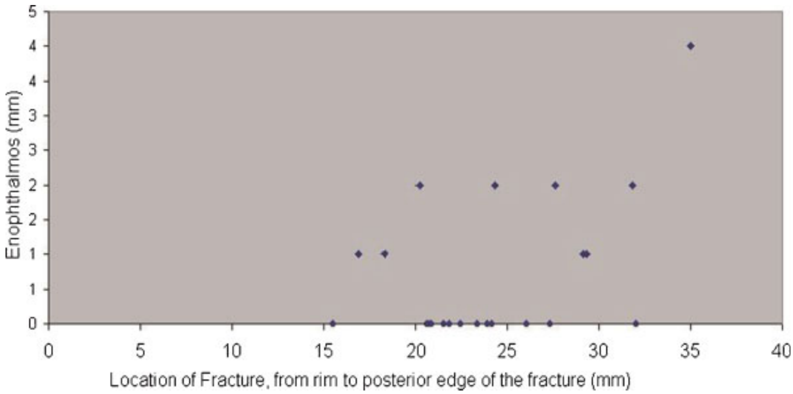


**Figure 11** Location of fracture from rim to the posterior edge of the fracture (*x*) by enophthalmos (*y*).

## DISCUSSION

In this study, we did not find any correlation between large changes in orbital volume and enophthalmos, nor did we did not find any statistical correlation between the herniated volume and enophthalmos. Additionally, in this study, we propose a new method for calculating the volume of the orbit and the herniated volume.

Earlier studies suggest that in a fractured orbital floor, an 18 to 20% expansion of the bony orbital volume compared with the unfractured orbit could be a criterion for surgery due to an increased risk of enophthalmos and subsequent diplopia.[1,14,16] In our study, the only patient (No. 16 in Table 1) who met this criterion of 18 to 20% volume expansion did not develop enophthalmos. However, there were still five patients who developed enophthalmos (mean 2 mm). Patient No. 19 in Table 1 had an orbital volume difference of 9.6% and developed a 4-mm enophthalmos. This indicates that the volume difference alone is an insufficient criterion for surgery. The hypothesis of an 18% expansion is the result of a retrospective study of 16 patients and therefore is of limited value.[1]

Earlier studies suggest that 1 mL of herniated orbital content would be followed by 1 mm of enophthalmos.[2,6,14] However, we did not find any statistical correlation between the herniated volume and enophthalmos ($r^2$ value). Six patients had herniated volumes of $\geq$1.5 mL, which is a current criterion for surgery. Three of six patients with larger herniated volumes did not develop enophthalmos. We observed that two of the patients who did develop enophthalmos (patients 15 and 19 in Table 1) had a posteriorly extended fracture compared with that of the patients with no enophthalmos. Our finding, therefore, is that the volume of herniation, as suggested in earlier studies,[1,14,17] is a questionable tool in the evaluation of patients with orbital floor fractures and that the location of the fracture and herniation may be more important than the actual volume. The probability of having a more posterior fracture localization seems to increase with a larger orbital volume.

Our finding that the correlation between relative orbital volume difference between orbits and the herniated orbital volume was poor might be explained by the hematoma in the maxillary sinus attached to the orbital soft tissue, which could be challenging to differ when measuring the orbital volumes. In the current study, only the volume of orbital and the herniated orbital soft tissue were measured.

Interestingly, several patients with a large herniated volume were underestimated by the radiologist at the initial calculation of the herniated volume. The radiologists usually measure the herniated orbital volume by calculating the length $\times$ width $\times$ height of the herniation. In collaboration with our radiologist, we suggest a new method of calculating the herniated volume using a computer-assisted soft tissue algorithm (see Appendix). In the control group, the relative volume difference between the orbits was 0.6 mL (0.1 to 1.4) and in percentage terms 2.5% (0.5 to 6.1%; Table 2), which is in accordance to earlier studies.[8,11] This indicates that the accuracy of our proposed method in measuring the orbital volumes is likely high and applicable in orbital volume measurement. The accuracy of the method needs to be validated.

Intermittent diplopia can be seen in the normal population with latent strabismus but the prevalence is unknown. In our study, 8 of 23 patients had intermittent diplopia (Table 1). We found that the diplopia in 50% of the patients was related to latent heterophoria (strabismus) rather than enophthalmos according to ophthalmologic examinations. The relative orbital volume change in patients with enophthalmos was 6.5%. Patients who did not develop enophthalmos had similar volume changes (6.4%). The contribution of enophthalmos to patients' diplopia development is unclear.

The strengths of our study are that we have introduced a new, more accurate method for calculating the volume of the orbit and orbital herniation with a high reproducibility. The CT scans we have used are $\leq$2-mm slices. Acceptable reliability was found for most orbital volume measurements for group comparison (ICC above 0.70) but not for individual comparisons (ICC between 0.90 and 0.95).

The weakness of our study is that it is retrospective. Eighty-nine patients were contacted via mail and only 48% (43 patients) responded and subsequently 20 patients were excluded due to medial orbital fractures or CT slices >2 mm, which left 23 patients being included. However, only a few studies have been performed,[2,17,18] and they have included fewer patients, except one.[19]

In conclusion, we have found that the relative volume change in the orbit or the herniated volume following an orbital fracture may be an insufficient criterion for surgery and that additional prospective controlled studies are required to evaluate the importance of the location of the fracture and the herniation as well as the mechanism of diplopia seen in some patients with orbital floor fractures.

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## APPENDIX

## THE MEASUREMENT OF THE ORBITAL VOLUME

Starting on the uninjured side on the axial CT slices, the optic nerve in the orbital channel was centered at its thickest (Fig. 3). The optic nerve's exit from the eye globe was marked with the cursor/red point as Point 1 (Fig. 3). In "Oblique" with a Fixing Point 1 as the center, the foramen opticus on both sides were centralized as widest. The lateral edge of the superior orbital fissure on the uninjured side was marked as Point 2 and the same structure on the contralateral side was marked as Point 3 (Fig. 3). Points 1, 2, and 3 together constituted a fixing platform during the rest of the volume calculation.

The posterior border was defined by eliminating the structures behind the line between the Points 2 and 3 (Fig. 3). To define the anterior border, in the same plane, the picture was scrolled to its widest and most distinct point of the lacrimal channel bilaterally and marked as Points A1 and A2 (Fig. 4). The lateral orbital limits were marked bilaterally as Points B1 and B2 (Fig. 4). The anterior borders were formed by eliminating the structures anterior to A1-B1 and A2-B2 (Fig. 4).

The volume of the orbital content was then measured by using the VR tools. Starting on the uninjured orbit on an axial slice cranially, the following steps were taken:

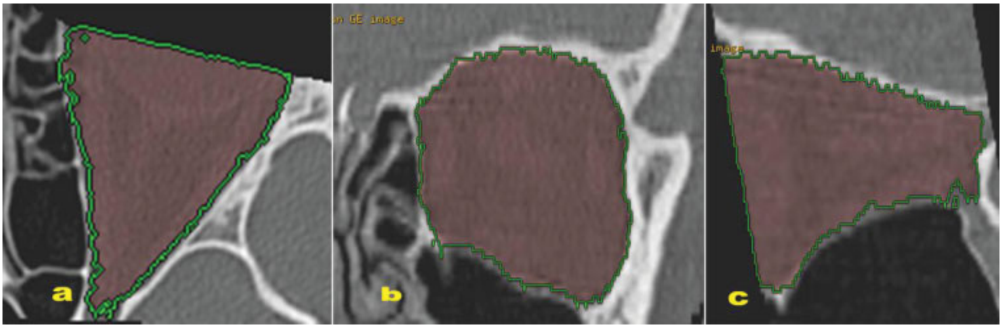



**Figure 12** Content of the orbit marked for the volume measurement: (A) axial slide, (B) coronal slide, (C) sagittal slide.

clicking on "VR tools"; "Add structure"; "Clear Destination"; the orbital content was marked with the mouse and left-clicked so that the area of interest was colored green. Then the slice was scrolled three to four steps caudally and the same procedure was performed until all the orbital content of interest was colored green. If any structure of no interest was colored green by mistake, the "Remove Structure" key was selected, and the areas were marked with the mouse by clicking the left button.

When the axial slices were completed, we moved to the coronal and then to sagittal slices and the same procedure was repeated (Fig. 12). To see the volume of the marked orbital content, "Display Tools" was clicked; the "Globe" key was selected and the marked orbital content was clicked. To exclude the bone structure, which may have been added, the "Threshold" was set between 0 and 200. Then by clicking on "Apply," the volume of the orbital appeared on the screen (Fig. 13). To calculate the content of the other orbit, the "Apply" key was clicked, then "Undo Apply T"; "3D tools"; "Auto Select"; "Clear Destination" before repeating the same steps to measure the contralateral orbit content.

The volume of herniated orbital soft tissue was measured as follows. The herniated orbital soft tissue was defined as orbital tissue herniated from the fracture edges of the orbital floor into the maxillary sinus. The hematoma underneath the herniated orbital soft tissue in the maxillary sinus was not included. The volume of the herniated orbital soft tissue was then measured by using the VR tools. Starting on the coronal slices, the herniated orbital soft tissue was marked anteriorly, and the following steps were taken: clicking on "VR tools"; "Add structure"; "Clear Destination"; the orbital content was marked with the mouse and left-clicked so that the area of interest was colored green. Then the slice was scrolled three to four steps posteriorly, and the same procedure was performed until all the orbital content of interest was colored green. If any structure of no interest, for example, hematoma, was colored green by mistake, the "Remove Structure" key was selected and the areas were marked with the mouse by clicking the left button (Fig. 1). When the coronal slices were completed, we moved to the axial and sagittal slices and the same procedure was repeated. To see the volume of the marked orbital content, "Display Tools" was clicked; the "Globe" key was selected, and the marked orbital content was clicked. To exclude the bone structure, which may have been added, the "Threshold" was set between 0 and 200.

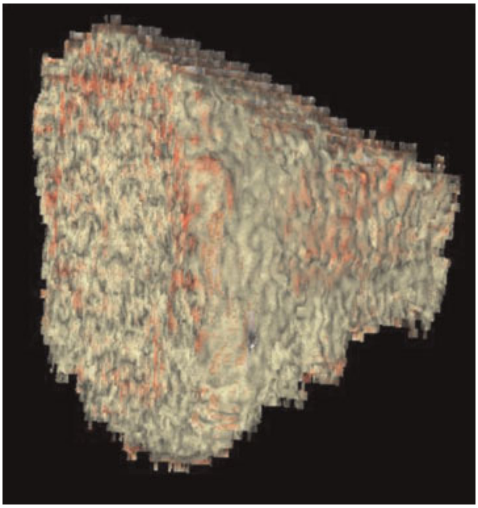
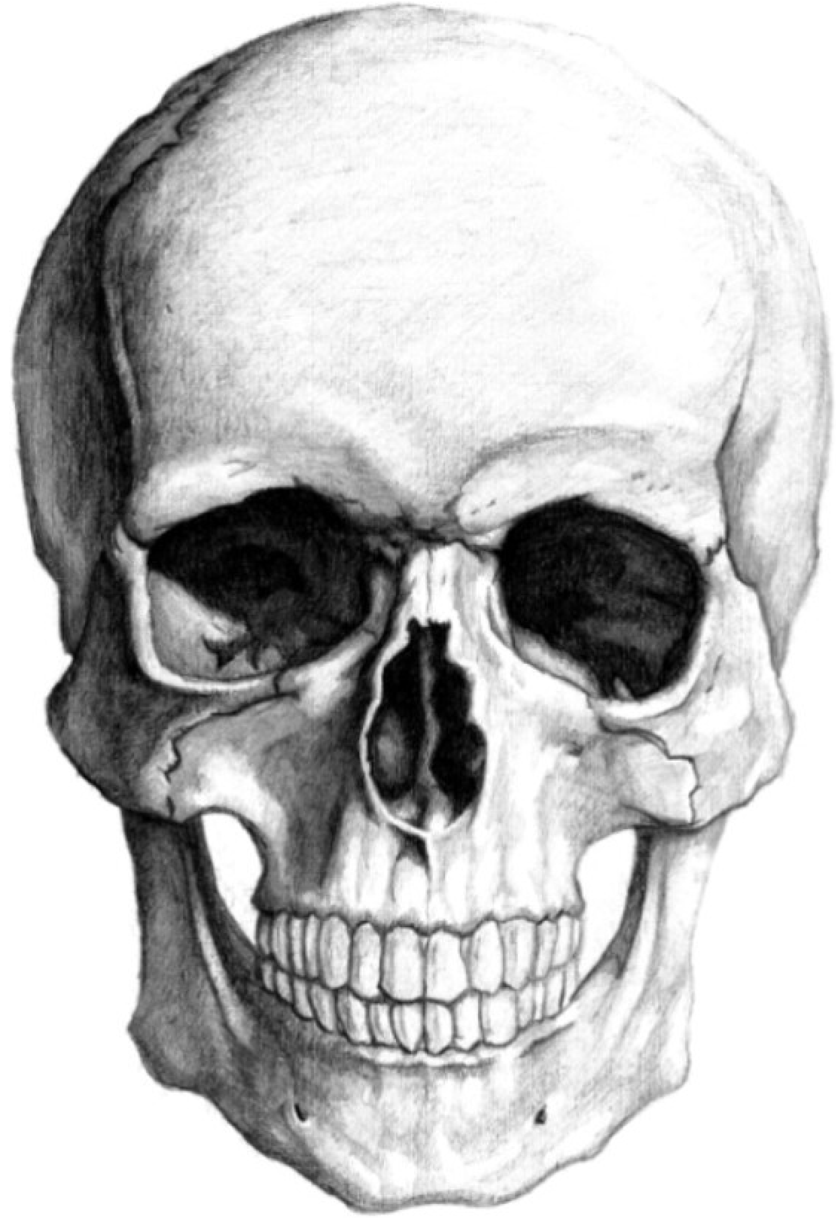


**Figure 13** The orbital volume.



# II

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# Still no reliable consensus in management of blow-out fracture

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ABSTRACT

*Background:* Management of blow-out fractures (BOF) is addressed by different specialties. The general agreement is that patients with the potential for late enophthalmus development require early surgical intervention. In this study we wanted to: (i) evaluate the differences in opinions between the specialties that manage BOF and also whether there was a difference between surgeons from different countries, (ii) evaluate if surgeons handle these cases based upon their own individual criteria,[1] (iii) evaluate the correlation between the management of patients with orbital floor fractures and any late sequelae detected upon eye examination.
*Materials and methods:* Eleven patients with BOF were selected from the records of the Department of ENT and Head & Neck Surgery, Karolinska University Hospital between 2003 and 2008. The cases were presented with a case history and CT scans to 46 surgeons from different countries and specialties and they were asked to give their opinions regarding the need for surgery, timing of surgery and the risk for late enophthalmus. We considered a group of surgeons to be in agreement if there was ≥75% agreement on whether or not to operate, when to operate and on the risk for late enophthalmus.
*Result:* The surgeons agreed on the choice of management for the patients (whether or not to operate) in only 5 of the 11 cases. Similarly, in only 5 of the 11 cases did the surgeons agree upon the risk for late enophthalmus. There was a greater difference between specialities than between physicians from the participating countries.
*Conclusion:* There are considerable differences in opinions regarding the management of BOF due to a lack of a reliable consensus. The management of BOF appears to be based on both individual and local traditions. Guidelines based on a randomized prospective study in BOF are required.


## Introduction

Isolated orbital floor fractures, also called blow-out fractures (BOF),[2] are a common injury from blunt facial traumas. Patients with BOF may suffer substantial sequelae both from the fracture per se, as well as from any surgical treatment. After many years of debate, there is still no reliable consensus regarding the optimal management of BOF.[1,3,4] This is mainly due to a lack of evidence, something that is very common in the surgical field. While recent studies have mostly focused on how to restore the orbital volume and rebuild the fractured orbital walls with high accuracy,[5,6] there is still no reliable evidence regarding surgical versus non-surgical treatment. The lack of evidence based guidelines creates difficulties for surgeons in deciding upon appropriate treatment, as well as being confusing for the patient.

Management of BOF is germane to a number of surgical specialities, including ENT surgeons, plastic surgeons, facial plastic surgeons, ocular plastic surgeons and oral maxillofacial surgeons.[1,3,8] Posttraumatic enophthalmus is a well-known sequela to BOF and is considered to be related to changes in orbital volume.[9–11] Early surgical intervention (24 h)[8,12] is imperative when other injuries threaten the eye such as nerve incarceration,[7] acute enophthalmus or hypoglobus,[13] and limitation of gaze caused by extra ocular muscle or periorbital tissue entrapment.[8,12,15,16] Late surgical intervention (1–4 weeks) is performed to prevent enophthalmus and hypoglobus, which can cause diplopia and cosmetic disturbances.[4,9,10] Furthermore, there seems to be a consensus that fractures where the orbital floor fragments are not displaced and the orbital volume remains unchanged can be left without surgical intervention.[7] However, the clinically problematic cases are those with a sufficient fracture size to permit the herniation of orbital fat and muscle as well as orbital volume change. In these cases the risk of possible surgical sequelae[17–22,26] has to be calculated against the risk for posttraumatic enophthalmus if left without surgical reconstruction.[9,10,23,29–31] Only a few papers have been published that address the surgical indications for exploration and reconstruction of BOF and there is no evidence as to which types of BOF have a potential for late enophthalmus.[4,7,9,16] Some of the dividing lines between surgical and

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non-surgical management that have been considered in the literature are: >1.5 ml volume of herniated orbital content into maxillary sinus,[9] a bony orbital volume expansion of 18% compared to the contra lateral orbit,[9] an orbital floor fracture >1 $cm^2$,[24,30] >50% fractured orbital floor,[29] diplopia 2 weeks after the trauma,[4] or an enophthalmus greater than 2 mm acute or after 6 weeks.[24] The "ideal" time to intervene surgically in BOF is also debated.[4,25] There are also surgeons who advocate a "wait and see" approach.[4,7,27,28]

In this study we wanted to: (i) evaluate the differences in opinion between the specialties that manage BOF and also whether there was a difference between surgeons from different countries, (ii) evaluate if surgeons handle these cases based on their own individual criteria,[1] (iii) evaluate the correlation between the management of patients with orbital floor fractures and any late sequelae detected upon eye examination.

## Materials and methods

From the patient records of the Department of ENT and Head & Neck Surgery, Karolinska University Hospital, 11 cases with CT-scan verified, unilateral isolated orbital floor fractures between 2003 and 2008, were randomly selected. At the Karolinska University Hospital approximately 20–30% of the isolated orbital floor fracture patients are treated with orbital floor reconstruction based on the herniated orbital content of >1–1.5 ml. Patients were contacted and invited to a clinical eye examination where they reported the presence of double vision or symptoms related to their eyes and vision. The clinical examination included an examination of diplopia and measurement of enophthalmus according to Hertel.[14]

Eleven cases with isolated orbital floor fracture were included. There were 7 men and 4 women. Eight patients had been treated non-surgically and three patients surgically. At the time of injury the patients had a mean age of 30 years (13–62). At the first visit after the injury two patients (cases 6 and 9) had diplopia, eight patients (cases 1, 2, 4, 5, 7, 8, 10, and 11) had no diplopi. In case 3, who had undergone strabismus surgery in childhood, it was unclear if the patient had diplopia or not. A power point presentation of each patient was prepared, based on summaries of the patients' first visit to the hospital including history and symptoms, findings on examination, the result of ophthalmologic examination and CT-scan slices of the fracture area, both in coronal and sagital projections. The 11 cases were presented to a total of 46 surgeons involved in orbital floor fracture management. Surgeons from different specialities and countries were recruited randomely from centers of excellence in trauma care. The specialities and countrys of origin are presented in Fig. 1.

The surgeons were asked to give their opinions as to whether surgery was necessary or not, the timing of the surgery and the risk for late enophthalmus. For subgroup analysis the participating surgeons were subdivided according to speciality and country of origin. The responses from the subgroups were compared. We considered the surgeons in a group to be "in agreement" if there was ≥75% agreement on whether or not to operate, when to operate or on the risk for enophthalmus. In analyses including all eleven patients, percent of overall agreement over all pairs of raters and kappa ($\kappa$) measure of agreement are provided. A rule of thumb is that a $\kappa$ of 0.70 or above indicates adequate interrater agreement. Randolph, J.J. (2008). Online Kappa Calculator. Retrieved from http://justus.randolph.name/kappa (June 7, 2012).

See Appendix for each case's history, examination, CT-scan and Ophthalmologic examination. This study was approved by the Local Ethics Committee at the Karolinska Institute.

## Result

The mean time from injury to the examination was 33 months (6–54). Three patients (cases 1, 9 and 11) developed 2 mm late enophthalmus and one patient (case 10) 4 mm late enophthalmus. At the follow up, 2 patients (cases 10 and 11) experienced intermittent diplopia, but no patient suffered from persisting diplopia. For details please see Table 1.

The experience level of the participating surgeons in BOF reconstruction was as follows: 3 surgeons (7%) had experience of 10 cases, 4 surgeons (9%) of 20 cases, 6 surgeons (13%) of 30 cases, 1 surgeon (2%) of 40 cases and 32 surgeons (70%) >40 cases of BOF reconstructions, see Fig. 2.

As to the question whether surgery was needed or not, all the surgeons were in agreement (≥75% agreed) in 5 of the 11 cases, and the overall agreement between all pairs of surgeons was 64%, $\kappa$ = 0.29. In the subgroup analyses for different specialities, the ocular plastic surgeons were in agreement in 3 cases (overall agreement 49%, $\kappa$ = −0.02), facial plastic surgeons in 5 cases (overall agreement 63%, $\kappa$ = 0.26), ENT surgeons (overall agreement 68%, $\kappa$ = 0.37) and oral maxillofacial surgeons in 6 cases (overall agreement 65%, $\kappa$ = 0.31), and the plastic surgeons in 10 cases (overall agreement 84%, $\kappa$ = 0.67). When looking at country of origin, we found that surgeons from USA and Sweden were in agreement in 5 (overall agreement 62%, $\kappa$ = 0.24), and 6 cases (overall agreement 68%, $\kappa$ = 0.35) respectively, while surgeons from Switzerland–Germany agreed on 9 cases (overall agreement 84%, $\kappa$ = 0.67). For details please see Fig. 3.

In the question regarding the risk for late enophthalmus, all the surgeons as a group were in agreement in 5 cases (overall agreement 62%, $\kappa$ = 0.23). Regarding the subgroups the facial plastic surgeons were in agreement in 4 cases (overall agreement 57%, $\kappa$ = 0.13), ocular plastic surgeons in 6 cases (overall agreement 62%, $\kappa$ = 0.24), ENT surgeons in 6 cases (overall agreement 67%, $\kappa$ = 0.32), and oral maxillofacial surgeons in 6 cases (overall agreement 60%, $\kappa$ = 0.20). Regarding country of origin, surgeons from the USA agreed in 6 cases (overall agreement 61%, $\kappa$ = 0.22),

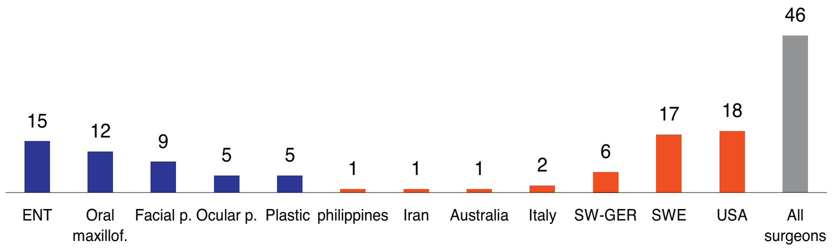


**Fig. 1.** The surgeons' speciality and country of origin.

**Table 1**
Summery of clinical findings and the surgeons opinions.

| Case | Diplopia at the first visit | Operated | Intermittent diplopia at the follow up | Late enophthalmus (mm) | ENT | Facial p. | Ocular p. | Oral maxillof. | Plastic | Ger–SW | SWE | USA | All surgeons |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | No | No | No | 2 | X, Y | X, Y | X, no risk | X, Y | Surg, Y | Surg, sub risk | X, Y | X, Y | X, Y |
| 2 | No | No | No | 1 | X, no risk | X, Y | X, Y | X, Y | Surg, Y | Surg, sub risk | X, no risk | X, Y | X, Y |
| 3 | No | Yes | No | 0 | Surg, Y | Surg, Y | X, Y | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, Y | Surg, sub risk | Surg, Y |
| 4 | No | No | No | 0 | No surg, no risk | No surg, no risk | X, no risk | No surg, no risk | No surg, no risk | X, Y | No surg, no risk | No surg, no risk | No surg, no risk |
| 5 | No | No | No | 0 | X, Y | X, Y | X, Y | X, Y | X, Y | Surg, Y | X, Y | X, Y | X, Y |
| 6 | Yes | Yes | No | 0 | Surg, no risk | Surg, no risk | Surg, no risk | Surg, no risk | Surg, no risk | Surg, no risk | Surg, no risk | Surg, No Risk | Surg, no risk |
| 7 | No | Yes | No | 1 | Surg, sub risk | Surg, sub risk | X, Y | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, Sub risk | Surg, sub risk |
| 8 | No | No | No | 1 | X, Y | X, Y | X, no risk | Surg, Y | No surg, no risk | Surg, sub risk | X, Y | X, no risk | X, Y |
| 9 | Yes | No | No | 2 | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk | Surg, sub risk |
| 10 | No | No | Yes | 4 | X, Y | X, Y | X, Y | X, Y | Surg, sub risk | Surg, sub risk | X, Y | X, Y | X, Y |
| 11 | No | No | Yes | 2 | No surg, no risk | X. Y | No surg, no risk | X, no risk | Surg, Y | X, no risk | No surg, no risk | X, Y | X, no risk |

X – no agreement on management; surg. – agreement on surgery needed; no surg. – agreement on no surgery needed; Y – no agreement on the risk for late enophthalmus; sub. risk – agreement on substantial risk for late enophthalmus; no risk – agreement on small or no risk for late enophthalmus.

those from Sweden in 6 cases (overall agreement 66%, $\kappa = 0.32$), whilst surgeons from Switzerland–Germany agreed in 9 cases (overall agreement 72%, $\kappa = 0.43$).

All the groups were in agreement on the management, timing of surgery and the risk for enophthalmus in cases 6 and 9. Except ocular plastics, all groups were also in agreement on the management of case 3. In reality, cases 3, 6 and 7 underwent surgical intervention and at the follow up they had no diplopia and no enophthalmus. Case 9 refused surgical intervention and had 2 mm enophthalmus but no diplopia at the follow up. This patient was not interested in correction of her enophthalmus. For details please see Table 1.

In case 8 the oral maxillofacial surgeons and surgeons from Switzerland–Germany were in agreement that surgery was needed, plastic surgeons agreed that surgery was not needed, whilst there were no agreement between the other groups. In this case no surgery was performed and the patient showed no enophthalmus and no diplopia at the follow up. In case 5 the surgeons from Switzerland–Germany were in agreement for the need for surgery, whereas there was no agreement amongst the other groups. This case was treated non-surgically and showed neither enophthalmus nor diplopia at the follow up.

Except for the surgeons from Switzerland–Germany and plastic surgeons, no other group was in agreement regarding the need of surgery in cases 1, 2 and 10. Interestingly, case 10 is the only patient in this study who showed intermittent diplopia and 4 mm late enophthalmus at the 6 month follow up, a displacement of the bulb which is considered cosmetically disturbing and should have been operated at an early stage. In this case only the plastic surgeons and surgeons from Switzerland–Germany were in agreement that surgery was needed.

The surgeons from Switzerland–Germany advocated surgery in the 9 of the 11 cases, plastic surgeons in 8 cases, the oral maxillofacial surgeons in 5 cases, all the surgeons as a group, the ENT surgeons, facial plastic surgeons, surgeons from USA and Sweden in 4 cases and ocular plastics in 2 cases. When examining the opinions of the surgeons from Switzerland–Germany this group was in agreement that surgery was needed in 9 of 11 cases, but they did not agree that surgery was not needed in any of the 11 cases.

We also found that when the groups were in agreement that there was no or limited risk for late enophthalmus, they also agreed that surgery was not needed. The correlation between the need for surgery and the substantial risk for late enophthalmus was, however, only 73%.

## Discussion

In this study we found that there are substantial differences in opinions between surgeons, specialities and countries regarding the management of BOF. We also found that the treatment of BOF is based on individual and local traditions and that there is a very low congruence. Judging the risk for late enophthalmus was also very different between the surgeons, the specialties and the different countries.

In this study, we have used the definition of agreement as $\geq$75% of each fracture. We found that there was agreement in only 5 of the 11 cases of BOF when all individual surgeons were compared as one group. Surprising differences were seen in the management of BOF between the specialities. While surgeons from Switzerland–Germany would perform surgery in 9 of 11 cases and plastics surgeons in 8 cases, the ocular plastic surgeons would intervene surgically in only 2 cases. Regarding the remaining groups, the oral maxillofacial surgeons would operate in 5 cases, surgeons as a group, the ENT surgeons, facial plastic surgeons, surgeons from USA and surgeons from Sweden in 4 cases. If the definition of

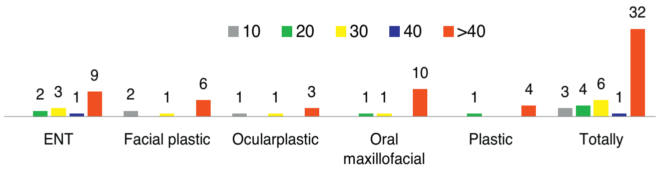


**Fig. 2.** Surgeons' experience in BOF reconstruction.

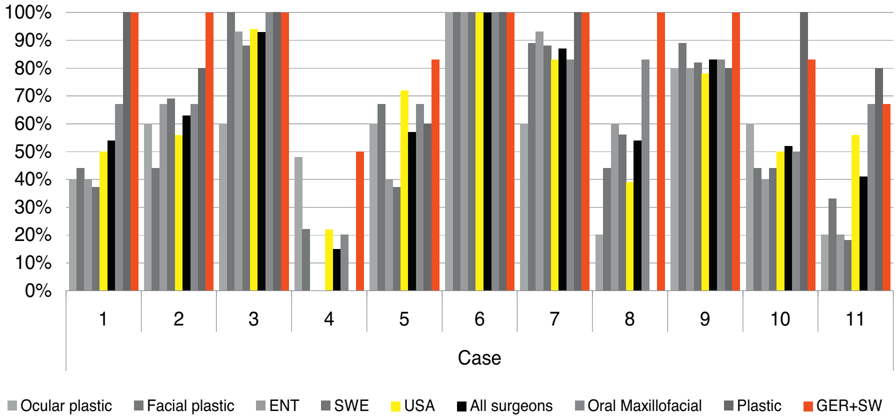


**Fig. 3.** Surgery needed.

agreement was set higher (100%) there were only two cases, cases 6 and 9, where the surgeons advocated the same therapy. Case (6) related to a 13 year old girl with an extra ocular muscle entrapment who was accepted for a surgical intervention within hours at the Karolinska University Hospital. In this case all of the surgeons were in agreement that there was a small or no risk for late enophthalmus. Indeed, this patient showed no enophthalmus at the follow up. Case 9, who refused to undergo surgery, showed a 2 mm enophthalmus but no diplopia at the follow up. This patient was not interested in correction of her enophthalmus.

Whether or not the patient had diplopia at an early stage did not affect the management decision. It is a clinical observation that diplopia in early stages, with no effect on extra ocular muscles, usually resolved within a short period of time.[4] We also found that when the groups were in agreement that there was no or limited risk for late enophthalmus, they also agreed that surgery was not needed. The correlation between the need for surgery and the substantial risk for late enophthalmus was, however, only 73%. Case 10, where the patient had a medial and an inferior orbital wall fracture resulting in an orbital volume increase, was not treated surgically and showed an 4 mm enophthalmus at follow up. Only the plastic surgeons and surgeons from Switzerland–Germany were in agreement that the risk for late enophthalmus was substantial and that surgery was needed. The other specialities were not in agreement, either on the need for surgery or on the risk for late enophthalmus. In such a case, with severe late enophthalmus, we anticipated to see a united agreement in all sub-specialities that surgery was needed and that the risk for late enophthalmus was substantial. It has to be mentioned that surgeons from Switzerland–Germany and plastic surgeons advocated surgery in most of the cases, 9 resp. 8 of the 11 cases. Our interpretation is that although the mechanism for the development of late enophthalmus has been studied and debated[5,10,31] for many years, there is still no common ground for the understanding of risk factors.

The agreement in risk for late enophthalmus was highest between the surgeons from Switzerland–Germany (9 of 11 cases) and lowest between facial plastic surgeons (4 of 11 cases). This may be explained by the fact that all the surgeons from Switzerland–Germany, were members of the AO-foundation, having similar indications for treatment, but only one of the facial plastic surgeons was a member of the AO-Foundation. There is no high level evidence suggesting surgical intervention decreases the risk for late enophthalmus.[9,29–31] Furthermore, the surgical complications reported need to be considered.[18,21,22]

We conclude that there is a very clear agreement in the surgical community that a BOF with extraocular muscle entrapment needs surgery within hours and that there is little or no risk for late enophthalmus in such a case. We conclude that some surgeons would perform surgery in almost all BOF cases whilst other surgeons would refrain from surgery, despite speciality or country.

## Limitations and strengths of this study

Weaknesses of the study are the recognised problems of observational studies as well as, in our case, a small population size and the use of a non-validated instrument. The strength of this study is that, even though we have a small sample size, it is substantial considering that we have 46 surgeons from different specialities and countries participating, which we feel is remarkable considering the well known reluctance of doctors to fill in forms.

Management of BOF seems to be based on both individual and local traditions. Despite the small sample size in this study, the results clearly show that there is a subjectivity in decision making among surgeons when evaluating BOF treatment and that there is still no consensus on the management of BOF. To clarify the existing confusion in the management of BOF our group has started a controlled randomized prospective study in BOF.

## Conflict of interest statement

The authors declared no conflict of interest. No external funding was received in the study.

## Appendix

**Case 1.** *History:* 52 y.o. woman who fell 1 day ago. Has no eye symptoms except swollen around the left orbita. *Examination:* Remarkable periorbital hematoma on the left side, no diplopia, normal extraocular motility, no obvious enophthalmus. *CT scan:* Orbital floor fracutre of the left side, a 15 mm displaced bone fragment dislocated 5 mm inferiorly. The fracture is 20 mm in the anterioposterior direction. Approximately 1 ml herniation. *Ophthalmologic examination:* No remarkable findings.

**Case 2.** *History:* 29 y.o. man assulted 11 days ago. *Examination:* Normal extraocular motility. No diplopia. Fuzzy vision when he looks down. *CT-scan:* Orbital floor fracture on the left side. A dislocated fractured bone fragment 11 mm in width and 11 mm in length, dislocated 11 mm inferiorly. Approximately 1 ml herniation. Inferior rectus muscle is lying on the boney edge, possible impigment. *Ophthalmologic examination:* No remarkable findings.

**Case 3.** *History:* 24 y.o. man assulted 1 day ago. Previously treated with strabismus surgery on the right eye. *Examination:* Periorbital hematoma on the right side and a slightly decreased eye motility, specially relating to upwards movement. *CT-scan:* Orbital floor fracture on the right side, inferior rectus muscle is dislocated into the maxillary sinus, indications of orbital muscle engagement. Approximately 1 ml herniation,. *Ophthalmologic examination:* Slightly decreased ability to look upwards with right eye, slight resistence at forced duction test, no great risk for eye damage.

**Case 4.** *History:* 13 y.o. girl, bicycle accident 2 days ago, has no eye symptoms. *Examination:* Periorbital hematoma on the left side, normal extraocular motility, no diplopia. *CT-scan:* Orbital floor fracture and lateral wall fracture on the left side, a 5 mm fractured bone in the middle part of the orbit, approximately 2 mm inferiorly dislocated, small herniation, inferior rectus muscle is not trapped. *Ophthalmologic examination:* No remarkable findings.

**Case 5.** *History:* 21 y.o. man, assaulted 1 day ago. *Examination:* Periorbital hematoma on the left side, the evaluation of the extraocular movement is not possible because of periorbital hematoma. *CT-Scan:* Posterior orbital floor fracture on the left side, no herniation, intraorbital air. *Ophthalmologic examination:* No enophthalmus, no diplopia, normal extra extraocular motility.

**Case 6.** *History:* 13 y.o. girl, a few hours before consult she hit her right eye with her knee while playing. Now double vision now pain in the right eye. *Examination:* Keeps her right eye closed, periorbital hematoma on the right side, double vision when looking with the both eyes but normal vision with one eye at a time, gets pain in her right eye when looking down, cannot elevate the right eye. *CT-scan:* Orbital floor fracture on the right side, inferior orbital muscle appears to be trapped in the fracture. *Ophthalmologic examination:* Positive forced duction test on the right side.

**Case 7.** *History:* 57 y.o. man, low speed motorcycle accident 2 days ago, no double vision. *Examination:* Periorbital hematoma on the left eye. Normal extraocular motility, no diplopi. *CT-scan:* Orbital floor fracture on the left side, a 25 mm fractured bone fragment is inferiorly dislocated. Approximately 2.0 ml herniated orbital tissue. *Ophthalmologic examination:* Normal extra ocular motility, no diplopia.

**Case 8.** *History:* 23 y.o. man, assaulted 4 days ago, had diplopia initially but better now. *Examination:* Diplopia in maximal gaze upwards. *CT-scan:* Orbital floor and medial wall fracture on the left side. Approximately 1.5 ml herniation of the orbital tissue. *Ophthalmologic examination:* No diplopia, normal extraocular motility.

**Case 9.** *History:* 29 y.o. woman, assaulted 1 day ago, has diplopia in all gaze directions. *Examination:* No periorbital hematoma, normal extraocular motility, diplopia in all gaze directions. *CT-scan:* Orbital floor fracture on the right side, the herniated orbital tissue including inferior rectus muscle is 2 cm $\times$ 1 cm $\times$ 2 cm. *Ophthalmologic examination:* Slightly decreased elevation on the right eye, no obvious muscle entrapment, normal vision.

**Case 10.** *History:* 28 y.o man, assaulted 2 days ego. *Examination:* Periorbital hematoma on the left side, normal extraocular motility, no diplopia, normal vision. *CT-scan:* Medial orbital wall fracture on the left side. Fracture fragments are protruding in the ethmoidal system on the left side. *Ophthalmologic examination:* No diplopia, normal extraocular motility.

**Case 11.** *History:* 31 y.o. man, assaulted 5 days ago. *Examination:* Normal extraocular motility, no diplopia. *CT-scan:* Orbital floor fracture on the right side, approximately 1.1 ml herniation of the orbital tissue. *Ophthalmologic examination:* No diplopia, normal extraocular motility.

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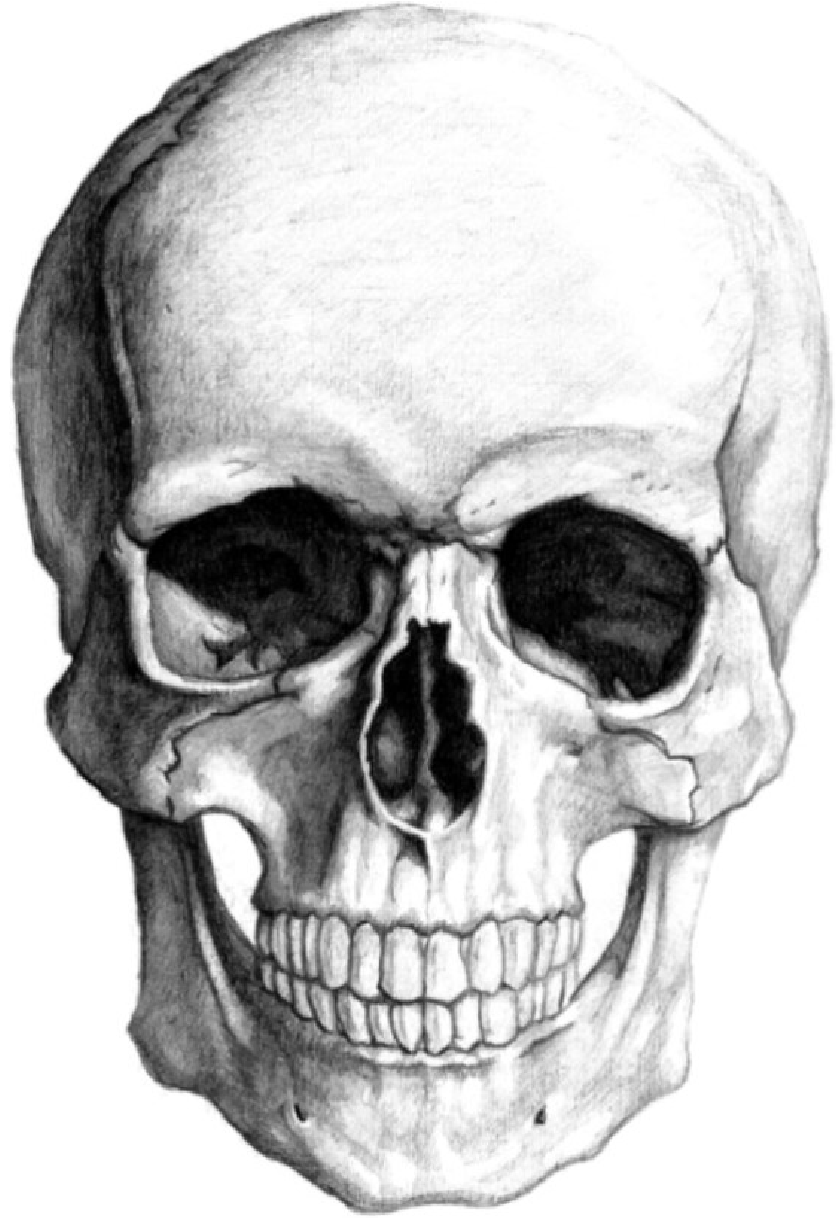

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# Prospective study on ocular motility limitation due to orbital muscle entrapment or impingement associated with orbital wall fracture

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ABSTRACT

*Introduction:* The recommended urgent surgical management of ocular motility restriction due to orbital muscle entrapment or impingement associated with orbital wall fracture needs to be elucidated.
*Aim:* To evaluate the importance of the time from injury to surgery for the outcome in ocular motility and diplopia, the time lapse of ocular motility, diplopia and hypesthesia recovery.
*Material and methods:* Patients with entrapment or impingement of orbital contents due to orbital wall fracture were followed up prospectively over 1 year regarding ocular motility, diplopia, hypesthesia and cosmetic deformity.
*Results:* 21 patients (10 entrapments and 11 impingements) were included and treated surgically. The median time from injury to surgery was 36 (8–413) h for the entrapment group and 168 (48–326) h for the impingement group. The median time from study inclusion to surgery was 0 (0–1) days for the entrapment group and 1.0 (0.2–4.8) days for the impingement group. All the patients had ocular motility limitation and diplopia at the inclusion. Ocular motility improved gradually and was normal at final visit. Diplopia resolved gradually in all patients except in two with non-disturbing diplopia, at the final visit. Forced duction test was positive in 90% of the patients in the entrapment group and 70% in impingement group. At final visit, hypesthesia was found in none of the patients in the entrapment group but in 4 patients in the impingement group.
*Conclusions:* In this, the first prospective long term follow up of orbital wall fractures with ocular motility restriction, we did not find any significant correlation between the time from injury to surgery and the outcomes in ocular motility and diplopia. An entrapment requires surgery as soon as possible; however, the surgical reduction is at least as important as surgical timing. Surgery should be delayed until it can be performed by an experienced surgeon. Ocular motility restriction causing diplopia due to impingement is not an ophthalmologic emergency and surgery is recommended if the diplopia and ocular motility has not improved over time. Clinical examination of ocular motility and not CT scan findings is crucial to determine whether a limitation of ocular motility exists or not.


## Introduction

In orbital wall fracture, orbital contents such as, fat, connective tissue or muscle may become herniated or entrapped within the fracture [1]. An entrapment of orbital tissue may result in ocular motility restriction [2]. This complication occurs more often in children due to the increased elasticity and flexibility of the bony orbit [3,4]. It has been recommended that an entrapped inferior rectus muscle should be released within hours [3] to prevent ischemia and scarring leading to permanent diplopia [5]. Entrapment of the inferior rectus muscle sheath and not the muscle itself has also been reported, but still clinically presents as restriction in ocular motility [6]. Although orbital blow out fracture (BOF) with herniation of the orbital contents is usually evident on computed tomography (CT) [7], certain BOF with ocular motility limitation can present with little or no abnormalities in imaging [8,9]. Entrapment of periorbital contents may appear in a trapdoor fracture, where entrapment refers to the soft tissues and the trapdoor to the type of bony injury (Fig. 1). In an open door fracture with a clinically verified ocular motility limitation, an impingement of the periorbital tissue would explain the prevention of normal eye movements (Fig. 2).

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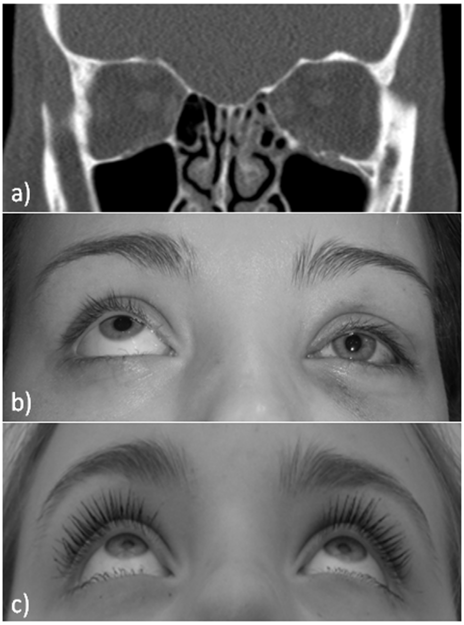

**Fig. 1.** CT scan (a) of a patient with left orbital wall fracture, with limitation to elevate the left eye 1 day after the injury (b), and normal eye movement at 1 year postoperative (c). This patient was considered to have entrapment of the left rectus inferior muscle.

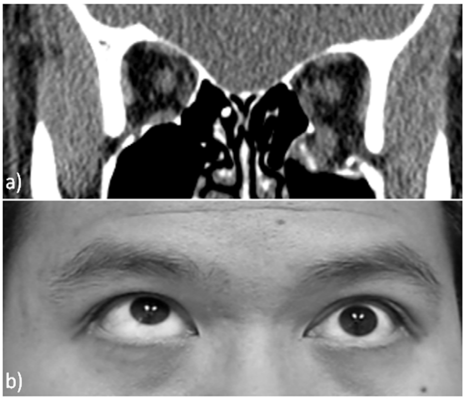

**Fig. 2.** CT scan (a) of a patient with BOF in left orbit with limitation to elevate the left eye, remaining 13 days after the injury (b). This patient was considered to have impingement of left inferior rectus muscle.

A motility restriction due to an entrapped inferior rectus muscle is commonly seen, however, the medial rectus may also be involved. These patients are more likely to present with paresis of the affected rectus muscle with restriction in adduction of the affected eye. In such a case similar recommendations to inferior rectus muscle entrapment apply, as in to release the entrapped muscle (Fig. 3) [10,11].

In this prospective study we aimed to evaluate: (i) the importance of the time from injury to surgery in relation to outcomes in ocular motility and diplopia, (ii) the time line for ocular motility and diplopia recovery and (iii) the degree of and recovery from hypesthesia.

*The ethics committee*

The Ethics Committee of the Karolinska Institute (EPN) Stockholm, Sweden, approved the study protocols and informed consent was obtained from each individual included in the study. The studies were conducted in adherence to the Declaration of Helsinki.

## Material and methods

This was a prospective observational study performed at the Department of Otorhinolaryngology and Head & Neck Surgery at the Karolinska University Hospital in Stockholm, Sweden. Patients with orbital trauma that presented with acute ocular motility limitation due to entrapment or impingement of orbital contents were asked to participate in the study between 2011 and 2016. All the included patients had clear ocular motility limitation in at least one direction and a CT scan verifying an isolated unilateral inferior, medial or inferomedial orbital wall fracture. Patients were treated according to current guidelines with urgent to early surgical intervention to release the affected ocular muscle and if needed a reconstruction the orbit.

After the inclusion, patients were followed for a minimum of one year with five clinical examinations. At each visit, patients completed a self-reported questionnaire and a clinical examination was performed by a physician for functional symptoms such as ocular motility, diplopia, hypesthesia of the infraorbital nerve, as well as cosmetic deformities such as enophthalmus, hypoglobus and superior sulcus deformity. The measurement of enophthalmus was performed using a Hertel exophthalmometer [12]. Hypoglobus and superior sulcus deformity were noted if they were visible.

A forced duction test [13] was performed under general anesthesia prior and at the end of the surgery in order to determine whether ocular motility restriction was present or not. Patients were asked if they felt satisfied with the treatment they received at each visit. The patients' questionnaire and the physicians' protocol was study specific and have not been validated.

## Statistical analyses

All variables are expressed as median (10th and 90th percentile) or percentages, as appropriate. Statistical significance was set at the level of $p < 0.05$. Comparisons between two groups were

**Fig. 3.** CT scan of a patient with BOF in left orbit with limitation to adduct the left eye was observed 7 days after the injury. This patient was considered to have impingement of left medial rectus muscle.

assessed with the non-parametric Wilcoxon test for continuous variables and Fischer exact test or Chi square test for nominal variables. All statistical analyses were performed using statistical software SAS version 9.4 (SAS Campus Drive, Cary, NC, USA).

## Results

### *Clinical characteristics*

21 patients (9 female, 12 male) were included in this study. For clinical characteristics of the patients see Table 1.

There was a significant difference between the patients in the entrapment and the impingement group in baseline characteristics including age and cause of injury. The median age was significantly lower in the entrapment group compared to the impingement group. The most common cause of injury was sports injury in the entrapment group and falling and assault in the impingement group. There was no significant difference in the time from injury to inclusion or injury to surgery between the groups. However, there was significant difference in the time from inclusion to surgery between the groups.

The time from injury to inclusion varied from 0 to 16 days. Patients were followed up for at least one year after the injury: 1st visit (1–3 weeks post injury), 2nd visit (3–7 weeks post injury), 3rd visit (9–16 weeks post injury), visit 4th (21–32 weeks post injury) and visit 5th (50–68 weeks post injury).

All patients in both groups were satisfied with the treatment that they received at the final control.

### *Fracture characteristics*

#### *Entrapment group*

Ten patients with median age of 14 (11–23) years had ocular motility restriction and radiological signs of orbital wall fracture on the preoperative CT scan (Fig. 1).

#### *Impingement group*

Eleven patients with median age of 29 (17–77) years had ocular motility restriction and radiological signs of orbital BOF on the preoperative CT scan. In this group 4 patients had inferior wall fracture (Fig. 2), 2 patients had medial wall fracture (Fig. 3) and 5 patients had inferomedial wall fracture (Fig. 4).

### *Ocular motility limitation*

All the patients in the study had ocular motility limitation in at least one gaze direction at inclusion in this study. Postoperatively, ocular motility improved compared to that at inclusion. Motility

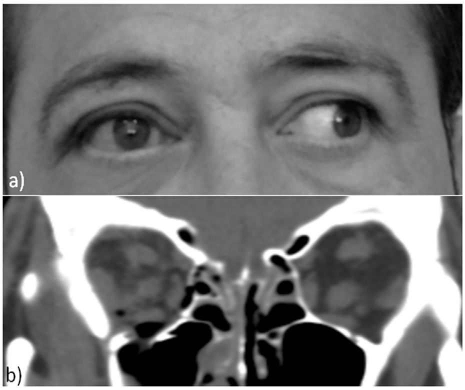


**Fig. 4.** CT scan (a) of a patient with inferomedial BOF of right orbit and paresis of right medial rectus muscle and limitation to adduct the right eye remaining 7 days after the injury (b). This patient was considered to have impingement of right medial rectus muscle.

**Table 1**
The patients were divided into two groups: Entrapment and Impingement. Continuous variables are expressed as median (10th and 90th percentiles) and nominal variables are expressed as percentages. [a] Calculated with Wilcoxon test, [b] Calculated with Likelihood test.

| Baseline characteristics | Entrapment (n=10) | Impingement (n=11) | P-value |
|---|---|---|---|
| Age, years | 14 (11-23) | 29 (17-77) | 0.0004[a] |
| Gender (F/M) | 5/5 | 4/7 | 0.52[b] |
| Injured Eye (L/R) | 6/4 | 5/6 | 0.50[b] |
| Cause of injury | | | |
| ➢ Falling | 0 | 4 | 0.002[b] |
| ➢ Physical assault | 0 | 4 | |
| ➢ Sports injury | 8 | 2 | |
| ➢ Traffic accident | 1 | 0 | |
| ➢ Other | 1 | 1 | |
| Time from injury to inclusion (days) | 1.5 (0-16) | 5 (1-12) | 0.31[a] |
| Time from injury to surgery (days) | 1.5 (0-16) | 7 (2-14) | 0.10[a] |
| Time from injury to surgery (hours) | 36 (8-413) | 168 (48-326) | 0.08[a] |
| Time from inclusion to surgery (days) | 0 (0-1) | 1.0 (0.2-4.8) | 0.006[a] |
| Fracture orbital wall ([1]inferior, [2]medial, [3]inferomedial) | [1] 10 (100) | [1] 4 (36), [2] 2 (18), [3] 5 (46) | 0.002[a] |

limitation was observed until the 2nd postoperative visit (3–7 weeks) post injury. It resolved gradually and was not observed in any of the patients at the 3rd, 4th or 5th (1 year) visits.

*Entrapment group*

All the patients had inferior orbital wall fractures with inferior rectus muscle involved. According to the physicians' findings, all the patients had limitation to elevate the injured eye. Three patients also had limitation to depress the injured eye. After surgery, ocular motility was normalized in 50% (n = 5) but partially remained in 40% (n = 4) of the patients and in 10% (n = 1) of the patient there was no improvement of the ocular motility at the 1st postoperative visit (1–3 weeks). This partial limitation was still found in 2 patients at the 2nd postoperative visit (4–7 weeks) post injury. At the remaining follow-up appointments, none of the patients showed any ocular motility limitations in any gaze direction.

One patient with entrapment of the inferior rectus muscle was operated on within 24 h. Two weeks after the initial surgery there was no improvement of the ocular motility. The patient was taken to the OR the same day. Forced duction test was similar to the ipsilateral unfractured side. When the orbital floor was explored again, entrapped connective tissue was found in the posterior end of the trapdoor fracture and released. One week after the re-exploration, the ocular motility had improved and was normalized at the 3rd visit (9–16 weeks).

When patients were asked at inclusion they all reported a sense of movement impairment of the affected eye. This decreased gradually and at the final visit only one patient reported affected eye movements but did not report any diplopia. However, eye movement restriction was not seen in the physicians' examination findings. Patients experienced ocular motility disorder in slightly higher frequency than the physicians' findings (Fig. 5).

*Impingement group*

5 patients had inferomedial BOF, 2 of them had medial rectus muscle impingement and 3 of them had inferior rectus muscle impingement. Four patients had inferior BOF with inferior rectus muscle impingement and 2 patients with medial BOF had medial rectus muscle impingement. All the patients with medial rectus impingement (n = 4) had paresis of adduction of the injured eye (3 right and 1 left). 7 patients had limitation to elevate the injured eye and 3 had limitation to depress the eye. Postoperatively, ocular motility limitation was only found in 2 patients up to the 2nd visit (3–7 weeks) after the injury. At the remaining follow-up appointments, none of the patients showed any ocular motility limitations in any gaze.

When patients were asked at inclusion 10/11 reported a sense of movement impairment of the affected eye. This decreased gradually and at the final control only two patients reported a sense of affected eye movement but neither of these two patients reported diplopia. However, eye movement restriction was not seen in the physicians' examination findings. Patients experienced ocular motility disorder in slightly higher frequency than the physicians' findings (Fig. 6).

*Diplopia*

*Entrapment group*

According to both the physicians' findings and patients' reports, all the patients had diplopia at inclusion. Diplopia was found in 7 patients at the 1st visit (1–3 weeks) post injury and in 6 patients at the 2nd visit (3–7 weeks) post injury. At the final visit, diplopia was resolved in all patients except in two, who reported diplopia in extreme upward gaze on examination. However, these two patients were back to normal life and had not been aware of their diplopia in extreme upward gaze. They were both 14 years old at the time of injury and were operated 4 and 5 days after the injury, due to doctor's delay. No ocular motility limitation or enophthalmus was observed or reported by these 2 patients (Fig. 7).

*Impingement group*

According to both the physicians' findings and patients' reports, all the patients had diplopia at inclusion. Diplopia was reported by 7 patients at the 1st visit (1–3 weeks), by 4 patients at the 2nd visit (4–7weeks), by 3 patients at the 3rd visit (12–16 weeks) and by 2 patients at the 4th visit (21–32 weeks) post injury. Diplopia was not reported at the final 5th visit in this group (Fig. 8).

*Time aspects*

The median time from injury to inclusion was 1.5 (0–16) days in the entrapment group and 5 (1–12) days in the impingement group. The median time from injury to surgery was 1.5 (0–17) days

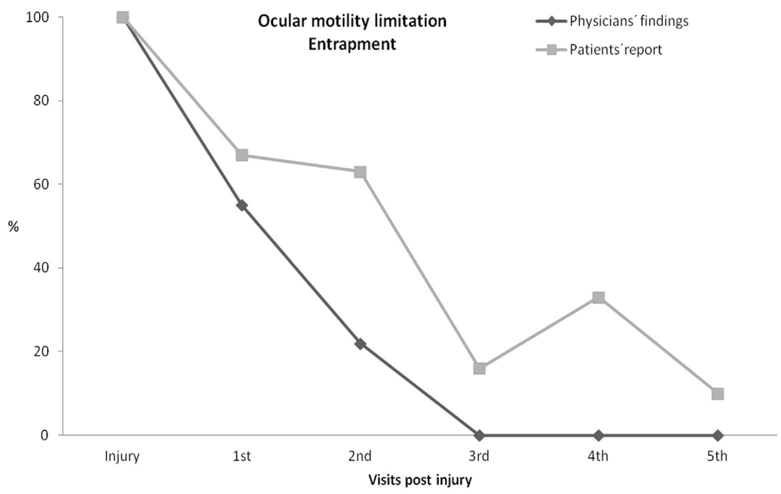


**Fig. 5.** Improvement in ocular motility in the entrapment group.

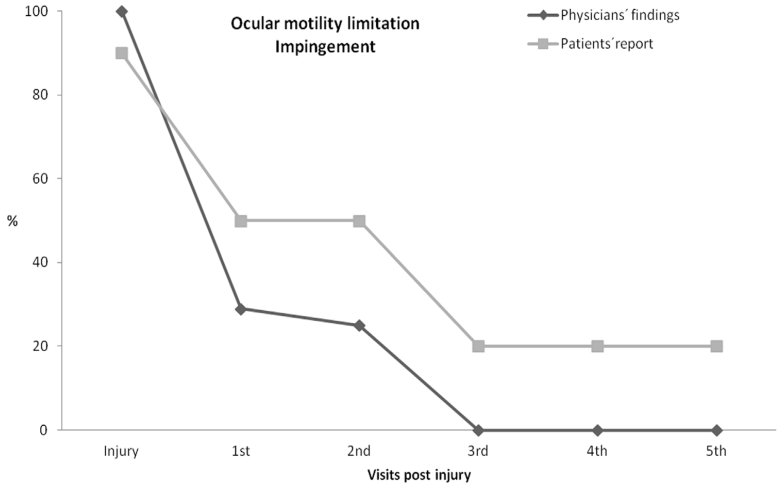


**Fig. 6.** Improvement in ocular motility limitation in the impingement group.

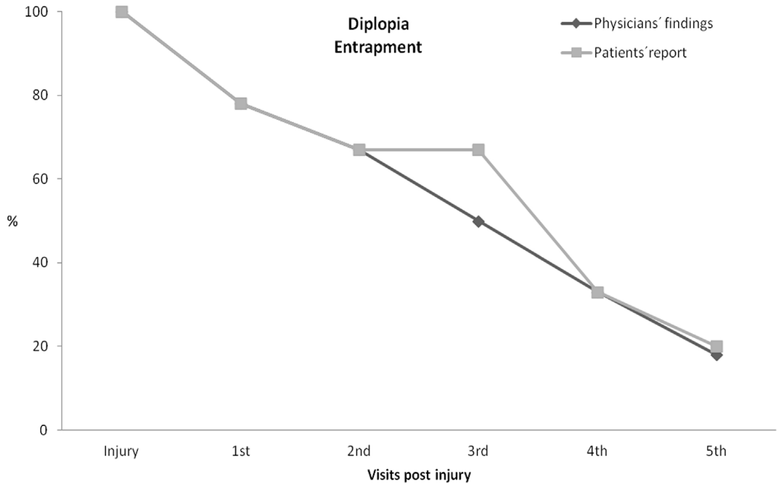


**Fig. 7.** Improvement of diplopia in the entrapment group.

or 36 (8–413) hours for the entrapment group and 7 (2–14) days or 168 (48–326) hours for the impingement group. There was a significant difference ($p = 0.006$) in median time from inclusion to surgery which was 0(0–1) days for the entrapment group and 1.0 (0.2–4.8) days for the impingement group, see Table 1.

In the entrapment group 5 patients were operated on within 24 h and 5 patients between 48 and 432 h. Despite guidelines that a patient with entrapped rectus muscle need surgical intervention within 24 h, the median time from injury to surgery was 1.5 (0–17) days in this group. Four patients underwent surgery 4–18 days post injury with the following reasons: One patient was injured in a ski accident in another country where a CT scan and MRI was performed and the patient was informed that there was no entrapment of ocular muscle. 4 days passed before the patient was admitted to our department and operated on the same day. In two of the cases there were doctors' delays due to inadequate ocular motility examination in addition to radiologic misinterpretation of the CT scan. In one case, patient delay was the reason for the late surgical intervention.

Two patients, both in impingement group had the longest waiting time from inclusion to surgery. One patient waited 7 days to stabilize a cardiac issue. In another patient there was a surgeon's delay of 4 days due to summer vacation.

We could not find any correlation between the time from injury to surgery and the ocular motility, diplopia and hypesthesia in any of the groups.

*Surgical intervention*

*Entrapment group*

Forced duction test was performed under general anesthesia prior to surgery in all patients and was found positive in 9 patients

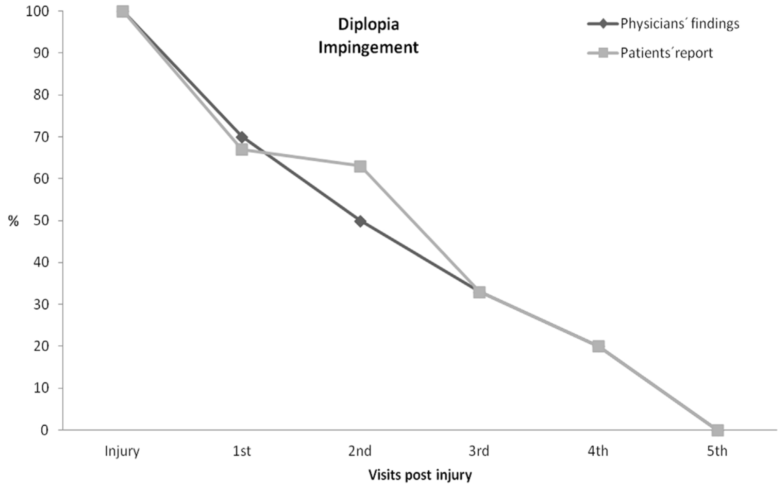


**Fig. 8.** Improvement of diplopia in the impingement group.

and negative in 1 patient. Through a transconjuctival approach, the orbital floor was exposed and the incarcerated orbital tissue was released from the trapdoor like fracture. The dissection was continued along the fracture by a few millimeters to 1 cm behind the posterior end of the fracture to make sure that there was no more incarcerated orbital tissue. No orbital implant was inserted. The surgery was completed by performing a new forced duction test. In all the cases the forced duction test was negative.

The patient with a negative intra operative forced duction test was an 18 yo with radiological evidence of entrapment who was operated 17 days post injury. On discharge this patient had recovered totally from diplopia and ocular motility limitation.

*Impingement group*

Forced duction test was performed under general anesthesia prior to surgery in 9 patients and was found positive in 7 patients, negative in 2 patients (1 inferior and 1 medial rectus) and not performed in 2 patients (1 inferior and 1 medial rectus). Seven of the fractures required reconstruction by an orbital implant (SynPOR, titanium mesh titanium mash covered by polyethylene). The remaining 4 patients did not receive an implant due to the small size of the fracture.

*Hypesthesia*

*Entrapment group*

Hypesthesia was reported and observed in one patient at inclusion. Postoperatively, 2 patients had hypesthesia at the 1st visit (1–3 weeks) and 1 patient had hypesthesia at the 2nd visit (3–7 weeks) post injury. At the following visits none of the patients reported hypesthesia (Fig. 9).

*Impingement group*

At the inclusion, hypesthesia was observed and reported in 4 patients. One patient recovered from hypesthesia while one patient developed hypesthesia postoperatively. At the final visit

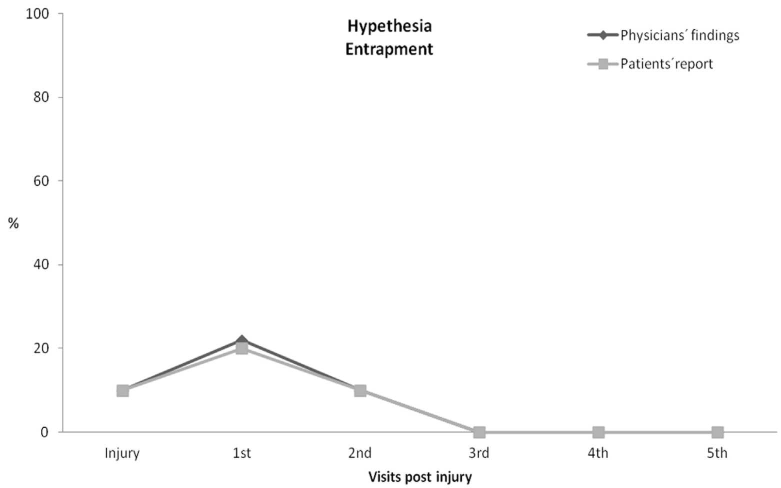


**Fig. 9.** Improvement in hypesthesia in the entrapment group.

4 patients still had hypesthesia. This finding was congruent with the patients report (Fig. 10).

*Visible deformity*

In one patient with muscle entrapment a 2 mm enophthalmus was found, but this was not observed by the patient. A new evaluation of this patient's CT scan showed that in addition to her trapdoor fracture in the orbital floor she had a medial BOF which was not reconstructed.

None of the other patients in the study developed visible deformity (enophthalmus, hypoglobus, superior sulcus deformity) either observed by the physician or reported by the patient.

## Discussion

To our knowledge this is the first prospective study of surgical treatment of patients with ocular motility limitation caused by entrapment and/or impingement of the inferior or medial rectus muscle due to orbital wall fracture, with a one year follow up. We could not find any significant correlation between the time from injury to surgery and the outcomes in ocular motility and diplopia. In fact, after surgical intervention ocular motility was normalized in all patients 3–7 weeks post injury.

There was a significant difference ($p = 0.006$) in median time from inclusion to surgery which was 0 (0–1) days for the entrapment group and 1.0 (0.2–4.8) days for the impingement group. There was also a difference in the medial time from injury to surgery for the entrapment group 1.5 (0–17) and for the impingement group 7 (2–14) days. This was due to local guidelines that a patient with entrapment receives surgical intervention within 24 h from the injury and a patient with impingement within a few days.

When analyzing the entrapment group in our study, we found no difference in examination findings between the 5 patients operated within 24 h and the 5 patients operated within 48–432 h after the injury. However, in two patients operated 4 and 5 days after the injury, the physician recorded diplopia in extreme upward gaze at the 1 year visit, even though the patients had not been affected by this in their normal daily life. This indicates that the importance of immediate surgery and the 24-h recommendation to operate on acute muscle entrapment may be debatable. In a retrospective study of 14 children with restriction of ocular motility the authors described a risk for necrosis of the entrapped muscle [5]. Furthermore, they found that 5 children had persistent motility impairment to the extent that they needed extra ocular muscle corrective surgery. Interestingly, the time from injury to surgery in the 5 children in this paper was similar to what we have described in our study where we only found one child with entrapment that had ocular motility impairment after surgery to an extent that warranted surgical exploration. On re-operation, we found that connective tissue surrounding the inferior rectus muscle remained entrapped. As a consequence our recommendation is that in patients with entrapment of orbital contents it is imperative to be extremely thorough on surgical exploration and in the case of persistent postoperative ocular motility restriction the first option should be surgical re-exploration to ascertain that the entrapped rectus muscle and orbital content are totally reduced. According to our experience small amounts of entrapped tissue may cause motility limitation but may not render a positive force duction test. Performing a force duction test before starting and at the end of the orbital procedure is highly important. In this study, there were documented force duction tests performed before the start and at the end of the surgery in 91% of the cases. Thus, the surgical reduction is at least as important as surgical timing. We still recommend surgery as soon as possible, however, the surgery should be delayed until it can be performed by an experienced surgeon.

We found that in the case of impingement of a rectus muscle causing motility disorder, surgical intervention is necessary, but not urgent, and that the patients will recover from symptoms even if operated on 14 days after injury. Our interpretation is that patients with ocular motility restriction causing diplopia due to impingement (not entrapment), are not ophthalmologic emergencies. An ocular motility examination one week post injury is recommended. Surgery is recommended if the diplopia and ocular motility is not improved at all. If there is some improvement, even minor, regular follow-up with appointments with 2–4 week intervals is recommended until this has normalized. If the motility limitations and diplopia remain and no recovery is observed,

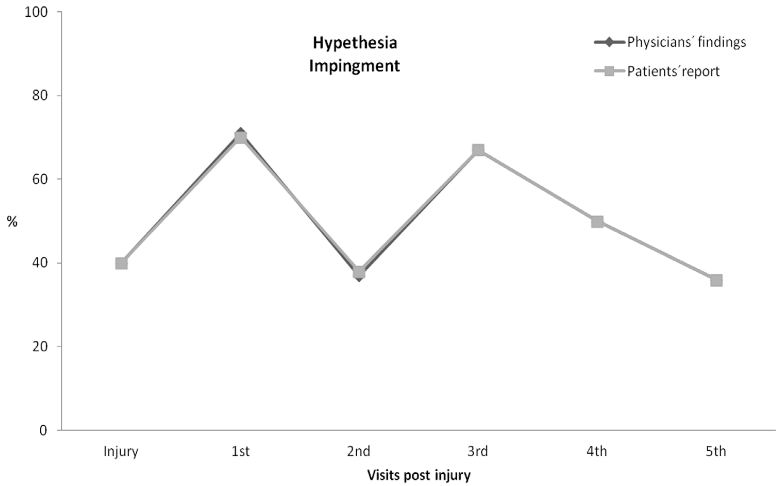


**Fig. 10.** Improvement in hypesthesia in the impingement group.

surgical intervention is recommended. This is not in agreement with earlier recommendations to "wait and see" when patients with BOF have persisting limitation of ocular movement and diplopia [5].

Patients with signs of entrapment had significantly lower age, 14 (11–23), compared to the impingement group who had higher median age, 29 (17–77). Accordingly, earlier reports suggest that inferior rectus muscle entrapment is seen only children [2,3]. However, in this study we included an 18 year old male with a negative forced duction test and a 23 year old female with positive forced duction test, both with inferior rectus muscle entrapment. Entrapment in a 19 year old patient has been reported earlier [5]. Similarly, entrapment of medial rectus muscle has been reported to be limited to the pediatric population [10]. However, in this study, we found impingement of the medial rectus muscle to be associated with medial BOF. The median age the patients with medial rectus impingement was 30 (16–49) years old.

Surgical treatment of 3 patients with entrapment was delayed due to "doctors' delay". In all three cases this was due to a misinterpretation of the CT scan by the radiologist together with an inadequate eye examination by the emergency physician. Our recommendation is that diagnostics of the ocular motility limitation have to be based on precise clinical eye examination and not on radiologic findings. By using a Q-tip, the swollen eyelids can be rolled away and the eye can be examined, see Fig. 11.

Entrapment involved only the inferior rectus muscle in inferior orbital wall fractures while impingement was found in inferior as well as medial rectus muscle in inferior, medial and inferomedial wall fractures. Interestingly, we found a difference in ocular symptoms in patients with inferior and medial muscle impingement. Patients with inferior rectus muscle impingement had limitation to elevate the injured eye and 3 of them also had limitation to depress the injured eye (paresis of the inferior rectus). Upon impingement of the medial rectus, paresis of adduction of the injured eye was the only ocular motility finding, which also has been reported in earlier studies [10,11].

None of the patients with entrapment had hypesthesia at the final visit. In the impingement group 4 patients had hypesthesia at the final visit which is in the range of the results from our earlier study of patients with BOF (submitted for publication) [14]. The hypesthesia may be due to the introduction of an orbital implant for the reconstruction of the fractured orbital wall, something that is important to consider when consenting the patient.

**Fig. 11.** The examination of the eye by using 2 Q-tips which are rolled inwards to roll away the eyelids.

In this study, only one patient developed a 2 mm enophthalmus which was observed by the physician and not the patient. This was a patient with an inferior rectus entrapment (Fig. 1) and a medial BOF that was not reconstructed. None of the other patients developed visible deformities (enophthalmus, hypoglobus or superior sulcus) which was not expected in the entrapment cases since there was no displacement of orbital content. In the impingement group, if there was a BOF and the herniation was measured to be more than 1.5 ml the orbital wall was reconstructed by an implant.

## Strenght and weakness

The strength of this study is that, as far as we are aware, this is the first prospective study of surgical treatment of patients with ocular motility limitation caused by entrapment and/or impingement with a one-year follow-up. Additionally, most of the clinical examinations were performed by one physician making the results reliable. Another strength is that all the included patients completed the study.

A weakness of this study is that non-validated instruments were used for physician's and patients' questionnaires. Hertel exophthalmomety has limitations and incorrect measurements can occur. There were no objective measurement of ocular motility and diplopia.

## Conclusions

In this, the first prospective long term follow up of orbital wall fractures with ocular motility restriction, we did not find any significant correlation between the time from injury to surgery and the outcomes in ocular motility and diplopia.

In an entrapment case we recommend surgery as soon as possible, however, the surgical reduction is at least as important as surgical timing and surgery should be delayed until it can be performed by an experienced surgeon.

Ocular motility restriction causing diplopia due to impingement is not an ophthalmologic emergency and surgery is recommended if the diplopia and ocular motility is not improved over time.

Clinical examination of ocular motility, and not CT scan findings, is crucial to determine whether a limitation of ocular motility exist or not.

## Conflict of interest

None.

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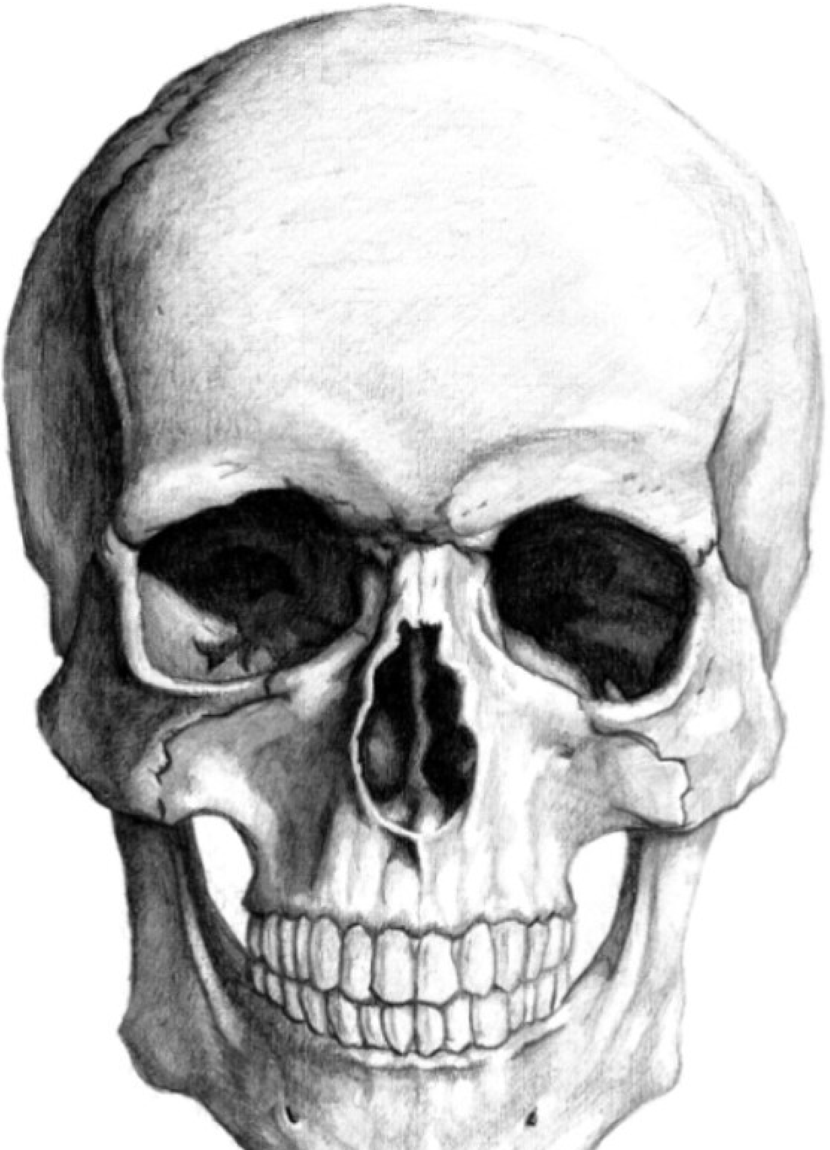

# IV

# New Algorithm for Management of Orbital Blow Out Fracture Based on Prospective Study

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Fracture area
Superior sulcus deformity
Hypoglobus

ABSTRACT

*Introduction*: Despite extensive debate and publications in the management of Blow Out Fracture (BOF), there are still considerable differences in the surgeons´ management of BOF due to a lack of reliable evidence based studies.
Aim: To evaluate which patients with BOF require an operation due to functional and/or cosmetic deformities and which computed tomography (CT) scan findings predict these problems. To provide an algorithm in management of BOF.
*Material and Method:* 79 patients with BOF were followed up prospectively regarding functional and cosmetic deformities for at least one year. The patients´ CT scans were analyzed and several measurements were performed. Patients´ symptoms and the clinical finding´s were correlated to the CT scan measurements.
*Results*: We found visible deformity in 37% of the patients but only 10% chose to proceed to surgery due to cosmetic deformities. In patients with inferior BOF and a herniation < 1.0 ml, a visible deformity was found when the ratio between fracture and the fractured orbital wall areas was ≥ 42%, or the total area of the fracture was ≥ 2.3 cm2. In patients with inferior BOF and a herniation ≥ 1.0 ml, a visible deformity was found when the distance from inferior orbital rim to the posterior edge of the fracture was ≥ 3.0 cm. In patients with inferomedial fracture a visible deformity was found when the herniation was ≥ 0.9 ml. Diplopia improved significantly and remained in only 3% of the patients in non-operated group. Hypesthesia of the infraorbital nerve improved significantly, but 22% of the non-operated and 50% of the operated patients still experienced loss of sensation at final control.
*Conclusions*: In this prospective study, we found that not only herniated orbital volume but other CT scan findings in BOF were crucial to predict late visible deformities. Based upon these findings we propose an algorithm for prediction of late visible deformity with 83% accuracy. There are indications that diplopia without ocular motility disorder is due to edema and we recommend observation as long as the diplopia improves gradually.

## Introduction

The standard management of isolated orbital wall fractures, also referred to as Blow out fractures (BOF), has been extensively debated over the years [1]. BOF can result in both functional and cosmetic symptoms. Potential functional symptoms include hypesthesia of the infraorbital nerve [2], diplopia [3] and ocular motility disorders [4]. Extra ocular muscle or periorbital tissue entrapment [4, 5], threatening the eye or the vision is an absolute surgical indication. The potential late cosmetic deformities include superior sulcus deformity, hypoglobus and enophthalmus [6, 7]. Surgeons predict the potential risk for functional and/or late cosmetic symptoms based on clinical and CT scan findings, knowing that not all BOF require surgical treatment [8]. The cut-off points between surgical and non-surgical treatment have been recommended at; > 1.5 ml volume of herniation [9] , an orbital floor fracture > 1.0 cm2 [10] or > 50% fractured orbital floor [11]. Despite recommendations on management [12, 13] there are considerable differences between surgeons, specialties and countries in opinions regarding the surgical vs nonsurgical management of BOF [14].

The aim of the study was to i) evaluate which patients with BOF, that are not operated on, develop functional and cosmetic problems ii) evaluate which

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CT scan findings can be used to predict late visible deformity in patients with BOF that are not operated on iii) provide an algorithm based on available evidence to predict which patients with BOF benefit from surgical vs non-surgical treatment.

The Ethics Committee of the Karolinska Institute (EPN) Stockholm, Sweden, approved the study protocols and informed consent was obtained from each individual included in the study. The studies were conducted in adherence to the Declaration of Helsinki.

## Material and methods

This was a prospective clinical study of patients with BOF at the Department of ENT and Head & Neck Surgery at Karolinska University Hospital in Stockholm, Sweden. Patients with facial trauma that presented with a CT scan verifying an isolated unilateral inferior, inferomedial or medial orbital wall fracture were included between the years 2011 and 2015. Patients with injuries threatening the eye such as extra ocular muscle entrapment were treated according to current guidelines and not include in this study.

After clinical examination and evaluation of the CT scans, patients who were not assessed to benefit from surgical intervention according to current guidelines at the Karolinska University Hospital were asked to participate in the study. The guidelines at Karolinska University hospital in BOF is surgical treatment if a herniation > 1.5 ml, due to risk for late enophthalmus and the decision is taken by a consultant.

101 patients were included. 22 of these patients did not complete the study. 79 patients were followed for a minimum of one year with up to six clinical examinations (week 0, 2, 4, 12, 24 and 52 or more post injury). The median time from injury to inclusion was 3 days (0-21), due to that most patients were referred from the emergency department. If a patient, during follow up, developed symptoms in need of surgical correction i.e. persisting diplopia or visible deformity such as hypoglobus, superior sulcus deformity or enophthalmus, surgery was offered. If surgery was performed, patients were followed for at least one year after surgery, see fig 1.

At each visit patients completed a self-report questionnaire and a clinical examination was performed by a physician for functional symptoms such as ocular motility, hypesthesia of the infraorbital nerve, diplopia, as well as cosmetic deformities such as enophthalmus, hypoglobus and superior sulcus deformity. Patients were asked if they felt satisfied with the treatment they received at each visit. The patients' questionnaire and the physicians' protocol was study specific and have not been validated.

Patients were categorized into three fracture types depending on which orbital wall were fractured:

1. Inferior wall fracture (medial to the infraorbital nerve and lateral to the inferomedial buttress),
2. Inferomedial wall fracture (both inferior and medial walls)
3. Medial wall fracture (medial to the interomedial buttress)

CT scan measurements (below) of patients with visible deformity were compared to patients with no visible deformity within each group and a Receiver operating characteristics (ROC) curve were used to determine the cut-off level for visible deformity in each fracture type, see table 1.

The CT scans were performed with ≤ 2mm slices, except in 4 patients with 3 mm slices, who were referred from another hospital. All CT scans of patients who completed the study were analysed for several measurements, see table 1. They were transferred to a workstation (GE Healthcare Advantage Workstation version 4) where the images were

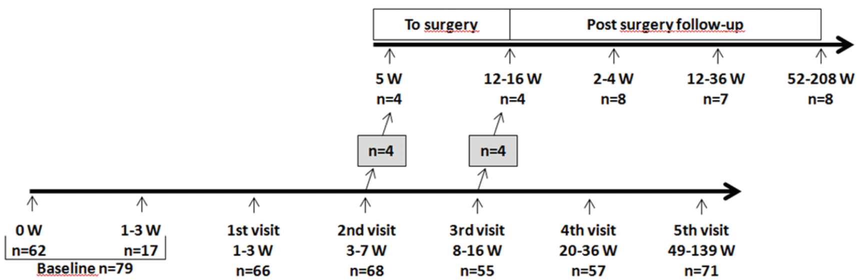


*Fig 1) Patient inclusion and flowchart. W=weeks.*

*Table 1. Patients with inferior wall, inferomedial wall and medial wall fracture with visible vs no visible deformity in comparison with CT scan measurements. ROC curve results (area under the curve) and cut-off points. a Calculated with Wilcoxon test, b Calculated with Fisher's exac t test. Paper IV.*

| | Inferior wall fractures (n=54) | | | | Inferior wall fracture with < 1.0 ml herniation (n=28) | | | | Inferior wall fracture with ≥ 1.0 ml herniation (n=26) | | | | Inferomedial wall fracture (n=18) | | | | Medial wall fracture (n=7) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CT-scan measurements | A) No Visible Deformity (n=38) | B) Visible Deformity (n=16) | P value A vs B | AUC/ (Cut-off point) | C) No Visible Deformity (n=24) | D) Visible Deformity (n=4) | P value C vs D | AUC)/ (Cut-off point) | E) No visible Deformity (n=14) | F) Visible Deformity (n=12) | P value E vs F | AUC/ (Cu- off point) | G) No Visible Deformity (n=7) | H) Visible Deformity (n=11) | P value G vs H | AUC/ (Cut-off point) | I) No Visible Deformity (n=5) | J) Visible Deformity (n=2) | P value I vs J |
| Inferior orbital rim to the anterior edge of the fracture (cm) | 0.8 (0.29-1.7) | 0.8 (0.1-1-6) | $0.834^{a}$ | 0.52 | 0.95 (0.3-1.8) | 0.65 (0.1-1.5) | $0.307^{a}$ | 0.66 | 0.4 (0.3-1.5) | 0.8 (0-2-1.6) | $0.097^{a}$ | 0.69 | 1 (0.1-1.5) | 0.6 (0.2-1.2) | $0.927^{a}$ | 0.51 | 0,6 (0.3-1.2) | 1.4 (1.3-1.5) | $0.052^{a}$ |
| Inferior orbital rim to the posterior edge of the fracture (cm) | 2.8 (2.2-3.1) | 3.1 (2.3-3.4) | $0.009^{a}$ | 0.72 | 2.7 (2.1-3.2) | 2.9 ( 2.4-3.3) | $0.390^{a}$ | 0.64 | 2.9 (2.6-3.1) | 3.1 (2.2-3.5) | $0.025^{a}$ | 0.75 (3.0 cm) | 2.9 (1.8-3-3) | 3.1 (2.0-3.5) | $0.202^{a}$ | 0.68 | 3 (2.4-3.6) | 3.6 (3.4-3.8) | $0.121^{a}$ |
| Length of the fracture (cm) | 1.9 (1.1-2.6) | 2.3 (1.5-2.6) | $0.051^{a}$ | 0.67 | 1.7 (1.0-2.5) | 2.2 (1.8-2.3) | $0.052^{a}$ | 0.65 | 2.4 (1.5-2.8) | 2.4 (1.1-2.6) | $0.815^{a}$ | 0.52 | 1.8 (0.8-2.8) | 2.4 (1.3-3.0) | $0.317^{a}$ | 0.64 | 2.1 (1.8-3.0) | 2.2 (2.1-2.3) | $0.845^{a}$ |
| Displacement of orbital bulge (mm) | 3.0 (0-7.7) | 3.2 (0-11.0) | $0.717^{a}$ | 0.53 | 2.9 (0-6.5) | 1.4 (0-5.4) | $0.409^{a}$ | 0.63 | 3.4 (0-11.3) | 3.7 (0-12.7) | $0.816^{a}$ | 0.53 | 1.9 (0-7.4) | 3.4 (0-5.7) | $0.412^{a}$ | 0.62 | 0 | 0 | |
| Dislocated fracture in medial buttress i=No, ii=Yes (n) | $36^{i}, 2^{ii}$ | $15^{i}, 1^{ii}$ | $0.885^{b}$ | | $22^{i}, 2^{ii}$ | $4^{i}, 0^{ii}$ | $0.423^{b}$ | | $14^{i}, 0^{ii}$ | $11^{i}, 1^{ii}$ | $0.270^{b}$ | | $5^{i}, 2^{ii}$ | $5^{i}, 6^{ii}$ | $0.274^{b}$ | | 0 | 0 | |
| Width of Fracture (cm) | 1.4 (0.9-2.0) | 1.7 (1.1-1.9) | $0.044^{a}$ | 0,67 | 1.3 (0.8-1.6) | 1.4 (1.1-2.0) | $0.528^{a}$ | 0.59 | 1.7 (1.3-2.3) | 1.7 (1.2-1.9) | $0.979^{a}$ | 0.50 | 1.8 (1.2-2.1) | 1.8 (1.2-2.5) | $0.715^{a}$ | 0.61 | 1.3 (1-1.8) | 1.1 (1.0-1.2) | $0.167^{a}$ |
| Ratio between the largest width of the fracture and the total width of the fractured orbital wall (%) | 59 (35-82) | 71 (42-90) | $0.016^{a}$ | 0.71 | 55 (32-70) | 63 (44-71) | $0.340^{a}$ | 0.65 | 68 (56-87) | 77 (46-96) | $0.571^{a}$ | 0.57 | 67 (50-100) | 74 (53-96) | $0.927^{a}$ | 0.48 | 72 (68-100) | 69 (67-70) | $0.118^{a}$ |
| Area of the fracture ($cm^2$) | 2.1 (1.2-3.5) | 2.7 (1.5-3.5) | $0.048^{a}$ | 0.67 | 1.7 (1.1-2.5) | 2.3 (1.9-2.6) | $0.048^{a}$ | 0.81 (2.3 $cm^2$) | 3.1 (1.7-4.3) | 3.0 (1.5-3.7) | $0.425^{a}$ | 0.59 | 3.6 (0.9-4.4) | 5.0 (3.0-6.9) | $0.020^{a}$ | 0.84 (4.8 $cm^2$) | 2.7 (1.2-3.7) | 2.6 (2.0-3.1) | $0.698^{a}$ |
| Ratio between fracture and the fractured orbital wall areas (%) | 37 (20-62) | 47 (28-61) | $0.038^{a}$ | 0.68 | 32 (19-40) | 42 (31-43) | $0.035^{a}$ | 0.83 (42%) | 52 (31-74) | 51 (24-63) | $0.503^{a}$ | 0.58 | 39 (8-45) | 44 (33-60) | $0.063^{a}$ | 0.76 | 53 (22-58) | 52 (42-62) | $0.438^{a}$ |
| Volume of the herniated orbital tissue (mL) | 0.9 (0.3-1.7) | 1.3 (0.7-2.7) | $0.001^{a}$ | 0.77 (1.0m) | 0.66 (0.2-1.0) | 0.8 (0.6-1.0) | $0.189^{a}$ | 0.65 | 1.4 (1.0-2.5) | 1.9 (1.1-2.9) | $0.149^{a}$ | 0.67 | 0.7 (0.4-0.9) | 1.5 (0.8-2.6) | $0.0007^{a}$ | 0.98 (0.9 ml) | 0.8 (0.3-2.0) | 1.2 (0.8-1.6) | $0.438^{a}$ |

evaluated in axial, coronal and sagittal planes in an osseous window level setting according to a previous study [15].

Measurements were made accordingly: Sagittal plane where the fracture was considered largest in the inferior wall:

i) the distance from the inferior orbital rim to the anterior edge of the fracture (fig 2A$^{i}$); on the same slice

ii) the distance from the inferior orbital rim to the posterior edge of the fracture (fig 2A$^{ii}$);, on the same slice;

iii) the longest antero-posterior length of the fracture (fig 2A$^{iii}$),

iv) the degree of displacement of orbital bulge in mm (fig 2B).

Coronal plane:

v) the largest width of the fracture and the wall (fig 2C$^{i, ii}$),

vi) the ratio between the largest width of the fracture and the total width of the fractured orbital wall on the same slice;

vii) the area of the fracture (fig 2D), respectively and;

viii) the total area of fractured orbital wall (fig 2E), respectively, and;

ix) the ratio between fracture and the fractured orbital wall areas;

x) the volume of the herniated orbital tissue (fig 2F),

xi) in medial wall fractures the supero-inferior extent of the fracture was measured as the width of the fracture and on the same slice the supero-inferior extent of the total wall (fig 2G$^{i, ii}$),

xii) if the inferomedial buttress was fractured and dislocated (fig 2H). Axial plane where the fracture was considered as largest in the medial wall:

xiii) the distance from anterior lacrimal crest to the anterior edge of the fracture (fig 2I$^{i}$); on the same slice

xiv) the distance from the anterior lacrimal crest to the posterior edge of the fracture (fig 2I$^{ii}$), on the same slice;

xv) the longest antero-posterior length of the fracture (fig 2I$^{iii}$).

## Area and volume measurements

All measurements were performed using the GE Healthcare Advantage Workstation version 4 (GE Healthcare, Milwaukee, WI).

*Area*

We performed a quantitative computational method for calculating the area of the fractures and the walls [16, 17]. Stacks of 2-mm slices were made in the coronal plane. The width of the inferior or medial orbital wall in each 2 mm-slice was measured. This resulted in trapezoidal strips with a known area (see fig 2E). The areas of the strips were multiplied to calculate the entire area of the wall. In the 4 cases where CT scan was performed with 3 mm slices the same procedure was followed, but instead made with 3 mm stacks.

The area measured was based upon the following landmarks: the medial border of the floor by the inferomedial buttress (fig 2J), the lateral border of the floor anteriorly at the point of the highest angle of the zygomatic bone and posteriorly by the medial edge of the inferior orbital fissure. The anterior border of the orbital floor was defined as the first slice that showed a measurable distance of the maxillary sinus. In the medial wall the starting point was the posterior lacrimal ridge and ending at the anterior sphenoidal wall. The cranio-caudal distance was measured between the inferomedial buttress and the ethmoido-frontal suture. Where the inferomedial buttress was displaced the measurement was estimated after comparison with the unfractured contra-lateral orbit (Fig 2J).

*Volume*

The CT scans used were axial raw thin slices in a soft tissue window setting (HU 600/1000) to distinguish blood from orbital fat and muscle tissue. The superior or lateral border (in medial fractures) was estimated. The contralateral orbit was used as a reference. Starting with the coronal plane the first slice that showed the fracture was chosen. The following steps were taken: “VR tools”; “Segment”;

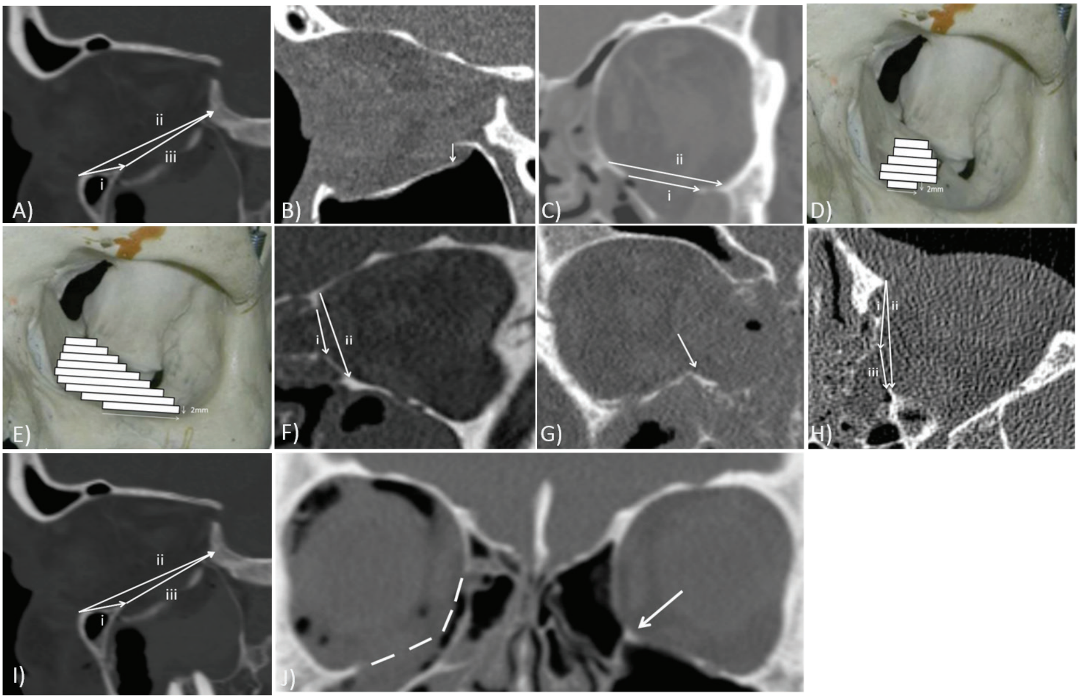


*Fig 2) A) Inf. orbital rim to: -ant. edge of the fx[i], -post. edge of the fx[ii] and the longest antero-posterior length of the fx[iii]. B) Displacement of orbital bulge. C) Largest width of the fx[i] and the orbital floor[ii]. D) Area of the fx. E) Area of the fractured orbital wall. F) Volume of the herniated orbital tissue. G) Supero-inferior extent of the fx[i] and supero-inferior extent of the wall[ii]. H) Medial buttress fractured and dislocated. I) Ant. lacrimal crest to -ant. edge of the fracture i, -post. edge of the fracture ii and longest antero-posterior length of the fx[iii]. J) Estimation of displaced Inferomedial buttress in comparison with the unfractured contra-lateral orbit and Inferomedial buttress (arrow).*

"Quick paint" with brush size 2 mm. The herniated content was marked green in one slice and then scrolled 2-3 steps posteriorly to mark the content again. In case of 2-3 mm slices only one step at a time was scrolled. This was repeated until all the content was marked in this plane. Then the same procedure was performed in the sagittal plane to fill in the gaps between the coronal slices. In the medial fractures the coronal and axial planes were used instead. The marked area was applied and the "Display tools" were used. The "Threshold" was set between -300 and 200 to exclude bone and air. To measure volume the "Globe" function was used.

**Statistical analyses**

All variables are expressed as median (10th and 90th percentile) or percentage, as appropriate. Statistical significance was set at the level of $p<0.05$. Comparisons between two groups were assessed with the non-parametric Wilcoxon test for continuous variables and Fischer exact test or Chi square test for nominal variables. Differences between three or more groups were analyzed with Kruskal Wallis test followed by Dunn´s test. Receiver operating characteristics (ROC) -derived area under the curve (AUC) values were used as cut-offs for statistical analyses followed by multinomial logistic regression analysis. All statistical analyses were performed using statistical software SAS version 9.4 (SAS Campus Drive, Cary, NC, USA).

**Results**

*Clinical characteristics*

79 patients completed the study. None of the patients had ocular motility limitation. 10% (n=8) of the patients choose to be treated surgically due to the development of a visible deformity (enophthalmus ≥ 2 mm and/or superior sulcus deformity and/or hypoglobus). The decision for surgery was taken when the deformity was notified at the visit 3-7 weeks post injury in 4 patients and at 8-16 weeks post injury in the remaining 4 patients, see fig 1. The baseline clinical characteristics are shown for patients who were operated on versus non-operated, see table 2. There was no significant difference between the patients in the non-operated and the operated group in baseline characteristics including gender, injured side, age, cause of injury and time to inclusion. However, the median age of the patients with BOF was 50 years (19-78) in the non-operated group and 30 years (12-73) in the operated group, but there was no significant difference (p=0.23). The most common cause of injury was falling followed by physical assault. 98 % (n=71) of the non-operated and 100% (n=8) of

| Baseline characteristics | Non-operated | Operated | P-value |
|---|---|---|---|
| | n=71 | n=8 | |
| **Age, years** | 50(19-78) | 30(12-73) | 0.23[a] |
| **Gender (F/M)** | 32/39 | 4/4 | 1.00[b] |
| **Injured Eye (L/R)** | 44/27 | 4/4 | 0.70[b] |
| **Cause of injury** | | | |
| ➢ **Falling** | 36(51) | 3(38) | 0.92[c] |
| ➢ **Physical assault** | 19(26) | 3(38) | |
| ➢ **Sports injury** | 8(11) | 1(12) | |
| ➢ **Traffic accident** | 2(3) | 0(0) | |
| ➢ **Bicycle accident** | 1(1) | 0(0) | |
| ➢ **Other** | 5(7) | 1(12) | |
| **Injury to inclusion, days** | 3(0-16) | 3(0-21) | 0.99[a] |
| **Satisfaction with treatment at final control, %** | 98 | 100 | 0.54[b] |

*Table 2) The patients were divided into two groups: operated and non-operated. Continuous variables are expressed as median (10th and 90th percentiles) and nominal variables are expressed as percentages, [a]Calculated with Fisher's exact test. [b]Calculated with Wilcoxon test, [c]Calculated with Chi-square test*

the operated patients were satisfied at the final control with the treatment that they received.

## Hypesthesia

*Non-operated group*

We found that, there was a significant improvement in hypesthesia from baseline according to both the physicians' findings (p=0.001) as well as the patients' self-reports (p=0.002). In the physicians' findings, 51% (n=36) of the patients had hypesthesia at inclusion and 18% (n=13) still had hypesthesia at final control. 49% (n=35) of the patients noted hypesthesia themselves at inclusion and 23% (n=16) had hypesthesia at final control.

*Operated group*

50% (n=4) of patients experienced hypesthesia according to the physicians´ findings at inclusion and at final control there was no improvement. According to the patients' self-reports, 63% (n=5) experienced hypesthesia at inclusion while 50% (n=4) experienced hypesthesia at the final control (week 52–208). There was no statistical significant improvement within the group at the final control compared to baseline, according to the physicians' findings as well as the patients' self-reports.

## Diplopia

*Non-operated group*

There was a significant improvement, according to the physicians' findings (p=0.0001) as well as the patients' self-reports (p=0.0002), in the number of patients experiencing diplopia at inclusion compared to final control. According to the physicians' findings, 33% (n=23) of the patients experienced diplopia at inclusion but only 3 % (n=2) had diplopia at final control. One patient had diplopia in up gaze (41 year old, inferomedial fracture with 0.5 ml herniation) and the other patient in down gaze (35 year old, inferior fracture with 0.9 ml herniation and 1.2 cm2 fracture area) and none of them had ocular motility limitation or a visible deformity at any visit. These two patients found their diplopia not disturbing to the degree that they wanted to proceed to surgery.

According to the patients self-report, 34% (n=24) experienced diplopia at inclusion and this remained in 7% (n=5) at final control. Patients experienced diplopia in slightly higher frequency than the physicians` findings.

*Operated group*

There was no statistically significant improvement, according to the physicians' findings (p=0.07) as well as the patients' self-reports (p=0.21), in the number of patients experiencing diplopia at inclusion compared to the final control. In the physicians' findings, 50% (n=4) of the patients experienced diplopia at inclusion and none experienced diplopia at final control. In the patients' self-report, 38% (n=3) of the patients experienced diplopia at inclusion while 13% (n=1) of the patients experienced diplopia at the final control.

## Enophthalmus

Twelve patients with 2 mm enophthalmus and six patients with ≥3 mm enophthalmus developed visible superior sulcus deformity and/or hypoglobus. Four patients in each group chose to undergo surgical correction. Seven patients with 2 mm enophthalmus did not develop visible deformity.

*Non-operated group*

We found a statistical significant (p<0.001) difference in the position of the eye on exophtalmometry during the study period (fig. 3). At the initial examination, the patients presented with exophthalmus or enophthalmus of the injured eye resulting in a median of 0 mm (range +4 to –2). The degree of

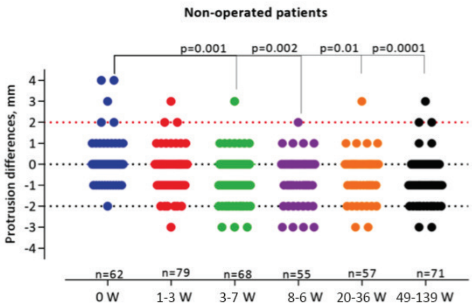


*Fig 3) Scattergram degree of enophthalmus in the non-operated group based on the physicians' findings. The p-values show the significance level between baseline and the different follow up times.*

enophthalmus increased during the study period and the patients were left with a median of 1 mm (range +3 to –3) enophthalmus at the final control.

*Operated group*

10% (n=8) of the patients received an operation due to a visible deformity with enophthalmus ≥ 2 mm and/or superior sulcus deformity and/or hy-

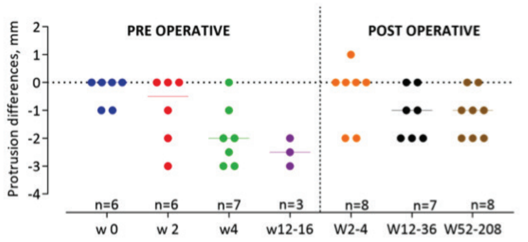


*Fig 4) Scattergram degree of enophthalmus in the operated group, pre- and postoperative, based on the physicians' findings.*

poglobus. The median time from date of injury to surgery was 71 days (31-112). The median degree of enophthalmus among these 8 operated patients was preoperatively 2.6 mm and post operatively at final control 1.0 mm (fig. 4), the same as for the patients that were not operated on. However, there was no statistically significant difference in the degree of enophthalmus at inclusion compared to the final control neither regarding physician's findings nor patients self-report.

## CT scan measurements

Depending on which orbital walls were fractured, patients were categorized as one of three fracture types: inferior wall, inferomedial wall and medial wall. 68% (n=54) of the patients had inferior wall fracture, 23% (n=18) inferomedial wall fracture and 9% (n=7) had a medial wall fracture. The results from CT-scan measurements were analyzed and compared between the patients with visible and no visible deformity within each fracture type, see table 1.

*Inferior wall fracture*

There were significant differences when comparing patients with visible and no visible deformity in: distance from inferior orbital rim to the posterior edge of the fracture (p=0.009), width of the fracture (p=0.04), ratio between the largest width of the fracture and the total width of the fractured orbital wall (p=0.01), total area of the fracture (p=0.048), the ratio between fracture and the fractured orbital wall areas (p=0.038) and the volume of the herniated orbital tissue (p=0.001). We used a ROC curve to determine the cut-off level for visible deformity in patients with inferior wall fracture. ROC curve results are presented in table 1. The highest ROC curve was for volume of herniated orbital tissue and the AUC was 0.77, giving a cut-off level at 1.0 ml. We sub-divided the patients into 2 groups, those with < 1.0 ml herniation and those with ≥ 1.0 ml herniation. The CT scan measurements were analyzed and compared within each group.

*Inferior wall fracture with <1.0 ml herniation*

There were significant differences when comparing patients with visible (n=4) and no visible deformity (n=24) in: total area of the fracture (p=0.048) and the ratio between fracture and the fractured orbital wall areas (p=0.035). A ROC curve for all the measurements predicting the visible deformity (n=4) was performed, see table 1. We found that AUC was 0.83 for the ratio between fracture and the fractured orbital wall areas giving a cut-off level at 42%. We also found that the AUC was 0.81 for the total area of the fracture giving a cut-off level at 2.3 $cm^2$.

In patients with inferior wall fracture and a herniation < 1.0 ml, a visible deformity was found when the ratio between the fracture and the fractured orbital wall areas was ≥ 42%, or the total area of the fracture was ≥ 2.3 $cm^2$.

*Inferior wall fracture with ≥ 1.0 ml herniation*

There was a significant difference when comparing patients with visible (n=12) and no visible (n=14) deformity in the distance from inferior orbital rim to the posterior edge of the fracture (p=0.025). A ROC curve for the distance predicting the visible deformity (n=12) was performed. We found that the AUC was 0.75 and the fracture distance from inferior orbital rim to the posterior edge of the fracture had a cut-off level at 3.0 cm, see table 1.

In patients with inferior wall fracture and a herniation ≥ 1.0 ml, a visible deformity was found when the fracture distance from inferior orbital rim to the posterior edge of the fracture was ≥ 3.0 cm.

*Inferomedial wall fracture*

There were significant differences when comparing patients with visible (n=11) and no visible (n=7) deformity in: the total area of the fracture (p=0.020) and the volume of the herniated orbital tissue (p=0.0007). ROC curves for both these two measurements predicting the visible deformity (n=11) were performed. We found that the AUC was 0.98 for the volume of the herniated orbital tissue, giving a cut-off level at 0.9 ml, and 0.84 for area of the fracture, giving a cut-off level at 4.8 $cm^2$, see table 1.

In patients with inferomedial fracture a visible deformity was found when the herniation was ≥ 0.9 ml.

*Medial wall fracture*

There were no significant differences in CT scan measurements when comparing patients with visible (n=2) and no visible (n=5) deformity, see table 1.

*Visible deformity*

Overall, visible deformity (superior sulcus deformity and/or hypoglobus and/or ≥ 3 mm enophthalmus) was found by the physicians in 37% (n=29) of the patients at 4 or 12 weeks follow ups, see fig 1. Of 29 (37%) patients with visible deformity, 26 patients had superior sulcus deformity (with 0 to -4 enophthalmus) 9 patients had hypoglobus (with 0 to -3 enophthalmus) and 6 patients were enophthalmic, see fig 5.

*Non-operated group*

Visible deformity was found by the physicians in 30% (n=21), of the patients, but only 13% (n=9) of the patients reported visible deformity at the final control.

*Operated group*

All the operated patients (n=8) had a preoperatively visible deformity according to both the physician´s and the patients´ report. Postoperatively at final control, physicians and patients reported visible deformity in 4 cases. But there were congruent opinions only in 2 cases between the physicians´ and patients´ report.

**Discussion**

This was, to our knowledge, the first prospective study of non-surgically treated BOF with a one year follow up. In this study we found certain CT scan characteristics with ROC cut-off points, for inferior and inferomedial wall fractures, which can be used when predicting the potential risk for late cosmetic deformities. Furthermore, we found that diplopia, not due to muscle entrapment, is benign and to a large extent will resolve within 1 year. However, hypesthesia of the infraorbital nerve is likely to remain.

We found that in inferior orbital wall fractures, when predicting risk for late deformity, a first cut-off point was ≥ 1.0 ml herniation. In patients with inferior orbital wall fractures and < 1.0 ml herniation, the next cut-off point was found to be if the ratio between fracture and orbital wall areas was ≥ 42%, or a fracture area of ≥ 2.3 $cm^2$. The ratio between fracture and orbital wall areas was found to be more


*Fig 5) 1 year post injury A) Left eye, 3 mm enophthalmus, B) Right eye, hypoglobus but no enophthalmus, C) Left eye, superior sulcus deformity and 2 mm enophthalmus.*

accurate (AUC=0.83), but this calculation is time consuming and challenging in daily clinical application. The area of the fracture although slightly less accurate (AUC =0.81) would be more practical in clinical use.

In patients with herniation ≥ 1.0 ml the distance from inferior orbital rim to the posterior edge of the fracture with an AUC 0.83, was found to be the next cut-off point. Visible deformity was found when this distance was ≥ 3.0 cm.

In inferomedial wall fractures we found that ≥ 0.9 ml of herniation would predict late visible deformity. The area under the AUC was 0.98 for this level (0.9 ml) making it highly sensitive and specific.

We found significant differences in the other CT scan measurements such as the width of the fracture, the ratio between the largest width of the fracture and the total width of the fractured orbital wall when comparing patients with and without visible deformity. However, we found that they had a low AUC rate making them less accurate predictors or usable cut-off points when predicting late visible deformity. Furthermore, we did not find any statistically significant difference in the distance from inferior orbital rim to the anterior border of the fracture, length of the fracture, displacement of orbital bulge or dislocated fracture in medial buttress when comparing patients with or without visible deformity.

Earlier studies have considered a herniation <1.0 ml to be a low risk for late cosmetic deformity [9, 18]. In this material, 14% (n=4) of patients with inferior wall and 22% (n=4) of patients with inferomedial wall fractures with <1.0 ml herniation developed visible deformity. Furthermore, 46% (n=12) of patients with inferior wall and 39% (n=7) of patients with inferomedial wall fractures with ≥ 1.0 ml herniation developed visible deformity. However, 21% (n=15) of patients with a herniation of > 1.0 ml did not develop a visible deformity.

In medial wall fractures we did not find any statistically significant difference in any CT scan measurements to predict late visible deformity. We believe that this was due to the low number of patients in this group (n=7).

According to the physicians findings, diplopia improved in all patients except two. Patients generally reported diplopia in a slightly higher extent than that of the physicians. Persistent diplopia with no ocular motility limitation has been suggested as a surgical indication in BOF [4]. A persisting diplopia may also be due to nerve injury [19], which may not be addressed with a surgical intervention. In this study we found that diplopia to a large extent resolves over time. This indicates that diplopia in BOF, without ocular motility limitation may be due to edema. We do not agree that the severity of diplopia increases with number of fractured orbital walls or with the extent of enophthalmus and that it would advocate surgical intervention within 2 weeks [20, 21]. Our recommendation is non-surgical treatment as long as the diplopia improves.

Although hypesthesia of the infraorbital nerve improved significantly at the final control, 23% of the non-operated patients still experienced loss of sensation. However, in the operated group, 50% of the patients had hypesthesia at the final control post operatively, which indicates that surgery may increase the risk of developing hypesthesia. It has been reported that hypesthesia of the infraorbital nerve may continue to improve even after one year following injury/surgery [22]. Earlier studies of facial fractures with infraorbital nerve damage have shown persistent hypesthesia in 22-50% after surgery [23]. Although other authors have hypothesized that hypesthesia may be an indication for repair of BOF [2] , we found that hypesthesia of the infraorbital nerve significantly improved over time and that surgery may increase the risk for persisting hypesthesia. Therefore, our recommendation is that hypesthesia is not an indication for surgery. Studies on hypesthesia with long follow up are an area of future research.

Of the 79 patients in our study 71 patients were not operated on. In the non-operated group, 30% developed a visible deformity. However, 98% of these patients were satisfied and no one wanted to have surgical correction. In the operated group (n=8) all patients choose to proceed with surgery because of late visible deformity. All these patients were also satisfied with the treatment they had received. Due to the small size of the operated group we recognize the difficulty in drawing conclusions from this data.

It is mentioned in the literature that the orbital bulge is the crucial anatomical structure in forward projection of the eye and that even a small fracture may lead to enophthalmus [24] and persistent diplopia [25]. Fracture in the inferomedial buttress has also been reported to lead to orbital deformity [26]. In this study we did not find any statistical difference in the degree of the displacement of the orbital bulge or the dislocated fracture in the inferomedial buttress when comparing patients with late visible vs non-visible deformity.

In our earlier study we found considerable differences in the management of the BOF [14], despite the published dividing lines between surgical and non-surgical management such as: > 1.5 ml volume of herniation into the maxillary sinus [9], an orbital floor fracture > 1.0 cm2 [10] or > 50% fractured orbital floor [11]. In the current prospective study, we suggest an algorithm (see table 3) with different cut-off points predicting the risk for late visible deformity.

According to our data this algorithm would lead to a correct prediction in 83% of patients, see the interpretation of data in table 4. In the remaining 17%, 8.5% would be over predicted and 8.5% under predicted. If the patients would be followed up 1, 3 and 12 months post injury/surgery (which we recommend), the initially under predicted patients would be identified at follow up and receive treatment. The over predicted patients may be operated on although they would not develop late visible deformity. If in patients with < 1.0 ml herniation, the ratio between fracture and orbital wall areas would be applied, the accuracy of correct prediction with this algorithm would increase to 86%, leaving only 5% of patients over predicted. However, calculation of ratio between fracture and orbital wall areas may be challenging and time consuming in clinical practice. Further studies are needed to minimize the risk for over prediction. The presented algorithm may be

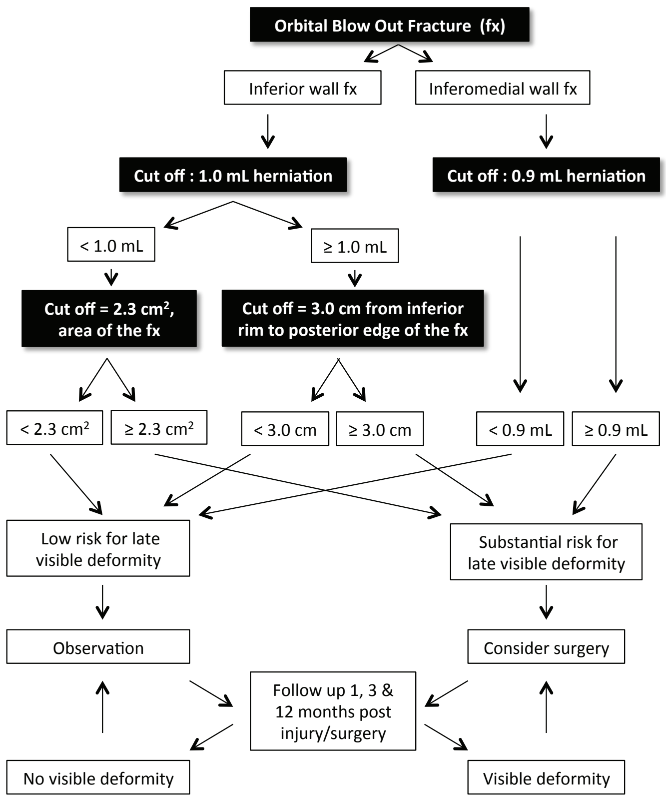


*Table 3) Algorithm predicting late visible deformity base on CT scan findings.*

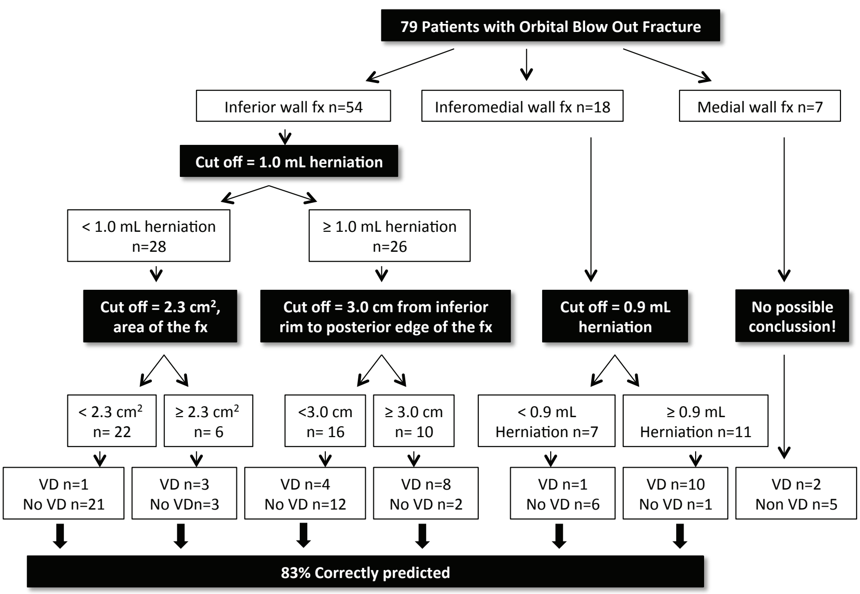


*Table 4) Interpretation of data. VD = Visible deformity, No VD = No visible deformity.*

used as a guide when discussing treatment options with patient with BOF fractures.

*Strengths and limitations of this study*

One strength of this study is that, as far as we know, this is the first prospective study on BOF with 79 patients followed up for over one year. Additionally, all the clinical examinations and the measurements on the CT scans were performed by one observer making the results predictable between patients.

A weakness of this study is that non-validated instruments were used for physician´s and patient´s questionnaires. Hertel exophthalmomety has limitations and incorrect measurements can occur. Another limitation is that 22% of the included patients dropped out. This was expected since it is likely that patients with no symptoms chose not to complete the study. This was a unicenter study with 79 participants and therefore a multicenter study that would include more patients would have great advantages.

## Conclusion

In this, the first large prospective long term follow up, we found that in addition to the herniated orbital volume other CT scan characteristics of BOF fractures are important predictors of late visible deformities. Using our data we present an algorithm for prediction of late visible deformity with 83% prediction accuracy. Diplopia in BOF, without ocular motility limitation, may be due to edema and observation is recommended as long as it improves.

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V

# Prospective Randomized Controlled Pilot Study on Orbital Blow out Fracture (BOF)

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ABSTRACT

*Introduction*: To clarify the conflicting recommendations for care of BOF a prospective randomized study has been required. Here we present a prospective randomized pilot study on BOF.
*Aim*: Evaluate which computed tomography (CT) findings predict late functional and/or cosmetic symptoms in BOF patients with ≥ 1.0ml herniation of orbital content into maxillary and/or ethmoidal sinuses. Evaluate which patients with BOF would benefit from surgical treatment or observational follow-up.
*Material and Methods*: 26 patients with BOF ≥ 1.0 ml herniation were randomized to observational (n=10) or surgical treatments (n=16) were followed up regarding functional and cosmetic symptoms for at least one year. The results from CT scan measurements were correlated to the patients´ symptoms and clinical findings which we report in this pilot study.
*Results*: Of the 10 patients randomized to observation, 5 had an inferomedial BOF with a herniation ≥ 1.3 ml and they all developed cosmetic deformities and required surgery. The remaining 5 patients in the observational group had inferior BOF and 1 of them had a distance of 3.3 cm from inferior orbital rim to posterior edge of the fracture and developed a cosmetic deformity but was unwilling to proceed to surgical treatment; and 4 patients had a median distance of 2.9 cm from inferior orbital rim to posterior edge of the fracture and did not develop cosmetic deformities. The median time from injury to surgery was 13 (3-17) days for the surgical group and 37 (17-170) for the patients that received an operation in the observational group. The surgical results were similar for all the operated patients at the final control. Diplopia decreased and remained partly in 1 patient in the surgical group and in 2 patients in the observational group. Hypesthesia of the infraorbital nerve decreased in non-surgically treated patients but surgery seemed to induce hypesthesia.
*Conclusions*: In this, prospective randomized controlled pilot study on BOF, all patients in the observational group with inferomedial fractures developed visible deformity. Diplopia in BOF, without ocular motility limitation, is believed to be due to edema. Diplopia is not an indication for surgery as long as it reduces over time.

## Introduction

Orbital blow out fracture (BOF) is a common finding in patients with facial trauma. It is well known that entrapment of extra ocular muscle is an absolute indication for immediate surgical intervention[1]. It is also known that BOF can result in considerable aesthetic deformities [2, 3], hypesthesia of the inferior orbital nerve [4] and chronic diplopia [5]. Early assessment of the significance of the fracture through clinical examination and imaging, and an informed decision between surgical or observational treatment, are crucial for an optimal result [6]. Due to the risk of late enophthalmus, hypoglobus and superior sulcus deformity, surgical correction has been considered to be required in the following cases: >1.5 ml herniation [7], cranial- caudal dimension of the orbit > 0.8 cm [8], an orbital floor fracture >1 cm2 [9], >50% fractured orbital floor [6], diplopia 2 weeks after the trauma [6] or an enophthalmus greater than 2 mm acute or after 6 weeks [9]. However, there are considerable differences in opinion regarding the management of BOF [10].

Recently, several studies have been published on different implants [11, 12] used in reconstructing orbital BOF's and orbital volume restoring with sophisticated devices [13, 14]. Which patient benefits from surgical or non-surgical treatment and timing

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of surgical repair is still unclear and remains surgeon and institution dependent [10]. To clarify the conflicting recommendations for care of orbital blow out fractures a prospective randomized controlled clinical trial is required. However, such a study has been considered to be difficult due to ethical aspects and recruitment of patients [15].

In this, prospective randomized controlled pilot study on BOF with a herniation ≥ 1.0 ml, the aims were to assess: i) which patients with BOF develop functional and/or aesthetic symptoms, ii) which CT scan findings predict late visible deformity, iii) which patients with BOF benefit from surgical vs observational treatment and iv) importance of timing for surgical repair.

The Ethics Committee of the Karolinska Institute (EPN) Stockholm, Sweden, approved the study protocols and informed consent was obtained from each individual included in the study. The studies were conducted in adherence to the Declaration of Helsinki.

## Material and methods

This was a prospective randomized controlled pilot study on orbital BOF with ≥ 1.0 ml herniation performed at the Department of ENT and Head & Neck Surgery at the Karolinska University Hospital in Stockholm, Sweden. Patients with facial trauma that presented with a CT scan verifying an isolated unilateral inferior or inferomedial BOF were included between 2011 and 2015. Patients with injuries threatening the eye such as ocular motility limitation were treated according to current guidelines and not included in this study.

After clinical examination and evaluation of the CT scans, patients with ≥ 1.0 ml herniation were asked to participate in the study. After the inclusion, patients were randomized to surgery or observation with follow with in a week. Patients were followed for a minimum of one year with five clinical examinations. If a patient in the observational group developed symptoms in need of surgical correction i.e. persisting diplopia or visible deformity such as hypoglobus, superior sulcus deformity or enophthalmus, surgery was offered and performed compatible to the surgical group. If surgery was performed, patients were followed for at least one year after surgery. Patients in surgical group underwent reduction of the herniated orbital content and reconstruction of the entire fractured orbital walls with orbital titanium reinforced porous polyethylene implants.

At each visit patients completed a self-reported questionnaire and a clinical examination was performed by a physician for functional symptoms such as ocular motility, diplopia, hypesthesia of the infraorbital nerve, as well as cosmetic deformities such as enophthalmus, hypoglobus and superior sulcus deformity. The measurement of enophthalmus was performed according to Hertel exophthalmometer [16]. Hypoglobus and superior sulcus deformity were noted if they were visible. Patients were asked if they felt satisfied with the treatment they received at each visit. The patients' questionnaire and the physicians' protocol was study specific and have not been validated.

*Table 1. Patients with inferior and inferomedial Orbital BOF, randomized to observation and surgery and subgroups with visible vs no visible deformity in comparison with CT scan measurements. a Calculated with Wilcoxon test, b Calculated with Fisher's exact test. VD = Visible deformity, No VD = No visible deformity. Paper V.*

| CT-scan measurements | Observational (n=10) (A) | Surgical (n=16) (B) | P value A vs B | Observational (n=6) VD (C) | Observational (n=4) No VD (D) | P value C vs D | Observational (n=1) inferior VD (E) | Observational (n=4) inferior VD (F) | P value E vs F |
|---|---|---|---|---|---|---|---|---|---|
| Inferior orbital rim to the anterior edge of the fracture (cm) | 0.6 (0.3-1.5) | 0.9 (0.5-1.6) | 0.22 a | 0.5 (0.4-0.7) | 1.2 (0.3-1.6) | 0.20 a | 0.4 | 1.2 (0.3-1.6) | 0.72 a |
| Inferior orbital rim to the posterior edge of the fracture (cm) | 3.0 (2.7-3.5) | 3.3 (2.6-3.6) | 0.13 a | 3.1 (2.9-3.3) | 2.9 (2.7-3.5) | 0.19 a | 3.3 | 2.9 (2.7-3.5) | 0.46 a |
| Length of the fracture (cm) | 2.5 (1.6-2.9) | 2.2 (1.6-3.0) | 0.69 a | 2.6 (2.3-2.9) | 1.8 (1.6-2.5) | *0.02* a | 2.9 | 1.8 (1.5-2.5) | 0.15 a |
| Displacement of orbital bulge (mm) | 3.4 (1.3-7.9) | 4.2 (0-9.8) | 0.71 a | 3.1 (1.2-6.6) | 4.8 (1.7-8.1) | 0.45 a | 2.5 | 4.8 (1.7-8.1) | 0.47 a |
| Dislocated fracture in inferomedial buttress i=No, ii=Yes (n) | 6 i, 4 ii | 12 i, 4 ii | 0.42 b | 2 i, 4 ii | 4 i, 0 ii | *0.04* b | 1 i, 0 ii | 4 i, 0 ii | 0 b |
| Width of Fracture (cm) | 2.0 (1.3-2.3) | 1.7 (1.3-2.2) | 0.56 a | 2.0 (1.8-2.3) | 1.4 (1.3-1.9) | *0.02* a | 2.0 | 1.4 (1.3-1-9) | 0.15 a |
| Ratio between the largest width of the fracture and the total width of the fractured orbital floor (%) | 70 (50-87) | 68 (55-89) | 0.46 a | 82 (69-87) | 61 (52-67) | *0.01* a | 83 | 61 (52-68) | 0.15 a |
| Area of the fracture ($cm^2$) | 3.9 (1.8-6.9) | 3.4 (1.9-5.4) | 0.56 a | 4.8 (3.8-7.2) | 2.2 (1.8-2.7) | 0.01 a | 4.0 | 2.2 (1.8-2.7) | 0.15 a |
| Fracture type: i=inferior, ii=inferomedial | 5 i, 5 ii | 9 i, 7 ii | 0.09 b | 1 i, 5 ii | 4 i, 0 ii | *0.003* b | 1 i, 0 ii | 4 i, 0 ii | 0 b |
| Volume of the herniated orbital tissue (ml) | 1.7 (1.3-4.0) | 2.2 (1.3-3.7) | 0.22 a | 1.8 (1.3-4.2) | 1.4 (1.3-2.9) | 0.21 a | 1.8 | 1.4 (1.3-2.9) | 0.65 a |

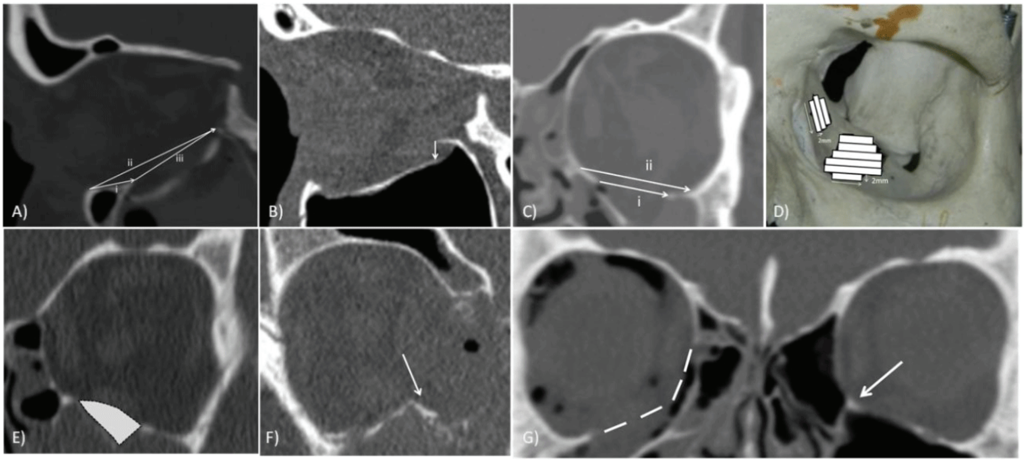


*Figure 1. A) Inf. orbital rim to: -ant. edge of the fx i, -post. edge of the fx ii and the longest antero-posterior length of the fx iii. B) Displacement of orbital bulge. C) Largest width of the fx i and the orbital floor ii. D) Area of the fx. E) Volume of the herniated orbital tissue F) Medial buttress fractured and dislocated G) Estimation of displaced Inferomedial buttress in comparison with the unfractured contra-lateral orbit and inferomedial buttress (arrow).*

The CT scans were performed with ≤ 2-mm slices. All CT scans of patients who completed the study were analysed for several measurements, see table 1. They were transferred to a workstation (GE Healthcare Advantage Workstation version 4) where the images were evaluated in axial, coronal and sagittal planes in an osseous window level setting according to a previous study [17]. The method we used in all measurement of the CT scans as well as figure 1 are described and used and in our other study (Submitted for publication) [18].

Measurements were made accordingly: Sagittal plane were the fracture was considered largest in the inferior wall: i) the distance from the inferior orbital rim to the anterior edge of the fracture (fig 1A[i]); on the same slice[ii]) the distance from the inferior orbital rim to the posterior edge of the fracture (fig 1A[ii]);, on the same slice;[iii]) the longest antero-posterior length of the fracture (fig 1A[iii]), iv) the degree of displacement of orbital bulge in mm (fig 1B). Coronal plane: v) the largest width of the fracture (fig 1C[i]) and the wall (fig 1C[ii]), vi) Ratio between the largest width of the fracture and the total width of the fractured orbital floor on the same slice; vii) the area of the fracture (fig 1D), viii) the volume of the herniated orbital tissue (fig 1E), xi) if the inferomedial buttress was fractured and dislocated (fig 1F).

*Area and volume measurements*

All measurements were performed using the GE Healthcare Advantage Workstation version 4 (GE Healthcare, Milwaukee, WI).

*Area*

We performed a quantitative computational method for calculating the area of the fractures [19, 20]. Stacks of 2-mm slices in the coronal plane were created. The width of the fractured orbital wall in each 2 mm-slice was measured. This resulted in trapezoidal strips with a known area (see fig 1D). The areas of the strips were combined to calculate the entire area of the fracture. Where the inferomedial buttress was displaced, the measurement was estimated after comparison with the unfractured contra-lateral orbit (Fig 1G).

*Volume*

The CT scans used were axial raw thin slices in a soft tissue window setting (HU 600/1000) to distinguish blood from orbital fat and muscle tissue. The following steps were taken: “VR tools”; “Segment”; “Quick paint” with brush size 2 mm. The herniated content was marked green in one slice and then scrolled 2-3 steps posteriorly to mark the content again. This was repeated until all the content was marked in this plane. Then the same procedure was performed in the sagittal plane to fill in the gaps between the coronal slices. In the medial fractures the coronal and axial planes were used instead. The marked area was applied and the “Display tools” were used. The “Threshold” was set between -300 and 200 to exclude bone and air. To measure volume the “Globe” function was used.

## Statistical analyses

All variables are expressed as median (10th and 90th percentile) or percentages, as appropriate. Statistical significance was set at the level of $p<0.05$. Comparisons between two groups were assessed with the non-parametric Wilcoxon test for continuous variables and Fischer exact test or Chi square test for nominal variables. All statistical analyses were performed using statistical software SAS version 9.4 (SAS Campus Drive, Cary, NC, USA).

## Results

*Clinical characteristics*

29 patients were included in this study. 3 patients from the observation group dropped out of the trial: one chose not to complete the study, one moved to another country and one patient died from unrelated causes. 26 patients completed the study, 10 in the observational group and 16 in the surgical group. None of the patients had ocular motility limitation at inclusion or at final control.

For clinical characteristics of the patients see table 2. There was no significant difference between the patients in the observational and the surgical group in baseline characteristics including gender, injured side, age, cause of injury and time to inclusion.

The most common cause of injury was falling followed by physical assault. All patients in both groups were satisfied with the treatment that they received at the final control.

All the 26 patients presented in this study had been at an inclusion visit, a one year follow-up visit and at least one more visit in between. In total, 26 patients were at the inclusion visit, 16 patients at the 1st visit (1-3 weeks post injury), 19 patients at the 2nd visit (3-7weeks post injury), 19 patients at the 3rd visit (10-16 weeks post injury), 14 patients at 4th visit (22-32 weeks post injury) and 26 at the 5th and final visit or final control (49-103 weeks post injury). For all included patients, the median time from injury to inclusion in the trial was 5 days (0-12). In the observational group, 6 patients developed a visible deformity with a median of 34 (16-150) days after the injury and 5 of these patients chose to proceed to surgery which was performed 37 (17-170) days after the injury. In the surgical group, the median time from injury to surgery was 13 (3-17) days.

| Baseline characteristics | Observation | Surgery | P-value |
|---|---|---|---|
| | n=10 | n=16 | |
| **Age, years** | 54(30-78) | 51(23-73) | 0.85[a] |
| **Gender (F/M)** | 3/7 | 7/9 | 0.49[b] |
| **Eye of injury (L/R)** | 4/6 | 5/11 | 0.20[b] |
| **Cause of injury** | | | |
| ➢ Falling | 6 | 8 | 0.54[c] |
| ➢ Physical assault | 3 | 6 | |
| ➢ Sports injury | 0 | 1 | |
| ➢ Traffic accident | 0 | 0 | |
| ➢ Bicycle accident | 1 | 0 | |
| ➢ Other | 0 | 1 | |
| **Injury to inclusion, days** | 6(0-12) | 4(1-12) | 0.23[a] |

*Table 2. The patients were divided into two groups: Observation and Surgery. Continuous variables are expressed as median (10th and 90th percentiles) and nominal variables are expressed as percentages. a Calculated with Wilcoxon test, b calculated with Fisher's exact test, c calculated with Chi-square test.*

**Diplopia**

*Observational group*

According to both patients´ and physicians´ report, 50% (n=5) of the patients had diplopia at inclusion and this remained with down gaze in 20% (n=2) of the patients at the final control. Due to hypoglobus and enophthalmus, these two patients proceeded to surgery 17 and 37 days after injury, respectively. No patient needed surgery due to diplopia.

Surgical group

Patients reported diplopia in 56% (n=9) of the cases and physicians in 50% (n=8) of the cases at inclusion. Diplopia remained in 6% (n=1) of the patients, which was observed in lateral gaze at the final control.

**Hypesthesia**

*Observational group*

According to both patients´ and physicians´ report, 60% (n=6) of the patients had hypesthesia of the inferior orbital nerve at inclusion and it remained in 40% (n=4) of the patients at final control. One patient developed hypesthesia after undergoing surgery.

*Surgical group*

According to both patients´ and physicians´ report, 50% (n=8) of the patients had hypesthesia of the inferior orbital nerve at inclusion. At final control, 4 of them still had hypesthesia and another 4 developed hypesthesia after undergoing surgery.

**Visible deformity**

*Observational group*

Visible deformity (superior sulcus deformity and/or hypoglobus and/or 3 mm enophthalmus) was found by the physicians in 60% (n=6) of the patients, 34 (16-150) days after the injury. 83% (n=5) of the patients with visible deformity had inferomedial BOF and they all chose to proceed with surgery. Surgery was performed 37 (17-170) days after the injury. Visible deformity was resolved in all patients who proceeded. 17% (n=1) of the patients with a visible deformity had an inferior BOF and chose not to undergo surgery.

*Surgical group*

None of the operated patients had a visible deformity at final control. The surgery was performed 13 (3-17) days after injury. In 2 patients, a slightly scleral show was found at the final control and the patients were not interested in surgical correction.

*CT scan measurements*

The results from CT scan measurements were analyzed and compared accordingly; observational group vs surgical group, the observational group with inferior BOF vs surgical group with inferior BOF, the observational group with inferomedial BOF vs the surgical group with inferomedial BOF, in the observational group whom developed visible deformity vs those who did not and finally the observational group with inferior BOF who developed visible deformity vs those who did not (see table 1).

We found a statistically significant difference when comparing the patients with inferomedial BOF in the observational and surgical groups: width of the fracture ($p= 0.004$) and the ratio between the largest width of the fracture and the total width of the fractured orbital floor ($p=0.01$), which most probably were due the fact that the study was underpowered.

*Observational group*

We found a statistically significant difference when comparing the patients in the observational group who developed visible deformity vs those who did not in: type of fracture ($p=0.003$), the length of the fracture ($p=0.02$), the width of fracture ($p=0.02$), the ratio between the largest width of the fracture and the total width of the fractured orbital floor ($p=0.01$), dislocated fracture in inferomedial buttress ($p=0.04$) and area of the fracture ($p=0.01$). All these significant differences were related to the type of fracture within these two subgroups.

5 patients had inferior BOF and 5 patients inferomedial BOF. Of the 6 patients who developed visible deformity, 1 patient had inferior BOF and 5 patients inferomedial wall fractures. Patients with inferomedial BOF had a herniation of 1.6 ml (1.3-4.2). This finding is in line with findings in our earlier studies which showed that with inferomedial BOF visible deformity is expected when the herniation is ≥ 0.9 ml (submitted for publication) [18].

With inferior BOF the median volume of the herniation was 1.8 ml (1.3-2.9) and the distance from inferior orbital rim to posterior edge of the fracture was 2.9 mm (2.7-3.5). 1 patient with an inferior BOF had a 3.3 cm distance from inferior orbital rim to the posterior edge of the fracture and developed a visible deformity. 3 patients with inferior

BOF had a < 3.0 cm distance from inferior orbital rim to the posterior edge of the fracture and did not develop a visible deformity. 1 patient with an inferior BOF had 3.5 cm distance and did not develop visible deformity. This observation is also in line with findings in our earlier study (submitted for publication) [18] that with inferior BOF visible deformity is expected when the distance from inferior orbital rim to posterior edge of the fracture is ≥ 3.0 cm.

*Surgical group*

9 patients had inferior BOF and 7 patients inferomedial BOF. The median volume of the herniation was 2.2 (1.3-3.7) ml and the distance from inferior orbital rim to posterior edge of the fracture was 3.3 (2.6-3.6) mm. For more details about the CT scan findings see table 1.

## Discussion

We present a prospective randomized pilot study on orbital BOF with ≥ 1.0 ml herniation. To the best of our knowledge, this is the first prospective randomized study on orbital BOF.

Although this is a pilot study, with a limited number of patients, we found significant differences between inferomedial and inferior BOF ($p=0.003$) when comparing patients who developed visible deformities to those who did not. All patients with inferomedial BOF who were randomized to observation developed visible deformities and they all proceeded to surgery, whereas 1/5 patients with an inferior BOF developed a deformity but chose not to have an operation. This later group needs to be studied further.

As described in our other study (submitted for publication) [18], we found that diplopia, without ocular muscle entrapment will to a large extent resolve. The diplopia is believed to be due to edema and as long as it decreases, there is no indication for surgery. A remaining diplopia can be due to nerve injury [21] which may not be addressed with a surgical intervention. We disagree with the suggestion that a BOF with diplopia, not due to ocular motility limitation, requires surgical intervention within 2 weeks [22].

Hypesthesia of the infra orbital nerve remain both in the observational and the surgical group and may persist after 1 year. However, we found that surgery could induce hypesthesia which therefore should be a part of patient informed consent. Our recommendation is that hypesthesia should not be an indication for surgery.

This randomized controlled study of BOF is unique most probably due to a long history of surgical intervention on all patients with substantial BOF. From earlier studies we concluded that the importance of the degree of herniation in development of enophthalmus was unclear [17]. In the design of the study we considered an orbital BOF with ≥ 1ml herniation as at risk for the development of enophthalmus [20, 23]. Furthermore, we hypothesized that a number of patients in this study with BOF would develop visible deformity if they were observed over time. From an ethical perspective it was therefore necessary to design the study so that if a visible deformity was discovered it would be corrected as soon as it developed. Our intention was that these patients would receive the same end result as if the patient was operated prior to the development of a visible deformity. Therefore we designed the study with continuous clinical controls with short time periods in between and patients were thoroughly informed about the importance of follow up. We do not feel that we have unnecessarily put patients at risk because there is lack of evidence based knowledge in the treatment of BOF. However, surgery was performed 37 (17-170) days after the injury in the patients in the observational group who developed visible deformity and chose surgical treatment. Visible deformity was resolved in all patients who proceeded. 17% (n=1) of the patients with a visible deformity had an inferior BOF and chose not to undergo surgery.

In earlier studies it has been described that inferomedial BOF has a high risk for development of visible deformity [5]. In this study we found that all patients in the observational group with inferomedial fractures developed visible deformity. They all opted for surgical treatment and at the one year follow-up none of them had a remaining visible deformity. This finding is in line with the findings in our observational study that with inferomedial BOF, visible deformity is expected when the herniation is ≥ 0.9 ml (Submitted for publication) [18]. Therefore we hypothesize that there is a fundamental difference between inferomedial and inferior BOF.

In our observational study we found that the size of the herniation alone could not predict the visible deformity in inferior BOF. In fractures with a herniation of ≥ 1.0 ml we found that a distance from the inferior orbital rim to posterior edge of the fracture ≥ 3.0 cm was important for the patients´ outcome whereas in patients with fractures with < 1.0 ml herniation the area of the fracture ≥ 2,3 $cm^2$ was predictive (submitted for publication) [18].

In the present study 4/5 patients with inferior BOF in the observational group did not develop visible deformity. Three of these patients had a fracture where the posterior fracture edge was < 3.0 cm from the inferior rim. This is in accordance with our earlier findings that a cosmetic deformity can be predicted in more than 80% with this type of fracture [18] (submitted for publication). Two patients with inferior BOF, where the fracture was ≥3.0 cm from the inferior orbital rim, were included in the study. One of the patients developed visible deformity whereas the other patient did not. The reason for this is still not understood and needs to be studied further. In this pilot study the number of patients with inferior BOF is still insufficient to clarify this issue. In the literature it has earlier been proposed that in BOF, a fracture > 50% of the orbital floor [6], an area of the fracture > 1.0 $cm^2$ [9] as well as a herniation > 1,5 ml [7] can be predictive for patient outcome. This could not be confirmed in the present study. However, in our earlier observational study these parameters have not been shown to correlate with development of a visible deformity (submitted for publication) [18].

In the literature, early surgical intervention in patients with BOF has been proposed to be important for patient outcome [6]. In our study the timing of surgery naturally differed between the observational and the surgical group. In the surgical group surgical correction was performed 13 (3-17) days after the injury while in the observational group 37 (17-170) days after the injury. In spite of this the surgical result was found to be satisfactory by the patients and also the physician in both groups. This may be interpreted that the surgical result from a late correction appears to be the same as in early corrections if the surgical correction is performed immediately after the visible deformity is discovered. Therefore we suggest a clinical control at least 1 and 3 months post injury.

*Strength and limitations of this study*

The strength of this study is that, as far as we are aware, this is the first prospective randomized study on BOF. Furthermore, in our opinion we have addressed the problems and difficulties with surgical randomised controlled studies. Additionally, all the clinical examinations and the measurements on the CT scans were performed by one physician making the results reliable.

Since this is a pilot study a limitation would be the low number of patient analyses. A weakness of this study is that non-validated instruments were used for physician´s and patient´s questionnaires. Hertel exophthalmomety has limitations and mis-measurements cannot be ruled out. Another limitation is that approximately 10% of the included patients did not complete the study.

Finally, all the patients in this study, have when asked been satisfied with the treatment they have received.

## Conclusions

In this prospective randomized controlled pilot study on BOF, we found that all patients in the observational group with inferomedial fractures had a herniation ≥ 1.3 ml and they all developed visible deformity. Diplopia in BOF, without motility limitation, is believed to be due to edema and it is not an indication for surgery as long as it decreases. Hypesthesia of inferior orbital nerve may remain and surgery may increase the risk for development of hypesthesia. Although ethically challenging we feel that randomized controlled studies of BOF are appropriate if one follows patients closely.

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